

Regulatory Competitive Shelters

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This Article identifies an array of seemingly disparate federal exclusivity regimes as belonging to an increasingly prevalent and relatively new class of highly valuable government benefits, which it names “regulatory competitive shelters” (RCSs). It characterizes RCSs and distinguishes them from other, more traditional kinds of government-instituted properties. The Article then proceeds to describe a particular brand of RCSs established in federal statutory frameworks whose aim—much like patents—is to create incentives for technological innovation. Identifying several common motifs of such RCS regimes, the Article offers a taxonomy of these RCSs and describes the mechanisms by which RCSs instituted under such regimes achieve their goals. Part III of this Article surveys—for the first time under a single title—all of the RCS regimes instituted to date in federal law which are aimed at promoting technological innovation. The Article concludes with a discussion of several aspects of RCSs that require further inquiry and will be further discussed in later articles.

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I. INTRODUCTION

Since the late 1970s, a new class of administrative intellectual properties has been quietly, almost secretly, emerging to fill gaps and support technological innovation where patents have fallen short. Known as “regulatory exclusivities,” “data exclusivities,” “market exclusivities,” “pseudo-patent exclusivities,” etc.,¹ these administrative benefits have received little attention in academic literature and remained, until recently, largely undertheorized. This Article, the first of three dedicated to these institutions, assembles, for the first time under a single title, these numerous administrative benefits. It offers a new name for them—regulatory competitive shelters (RCSs)—characterizes them, and describes them as an increasingly

¹ See *infra* Part II.D.

important class (rather than a disparate set) of regulatory institutions.² As RCSs aimed at creating incentives for technological innovation³ have been growing increasingly popular in recent years, it is likely that more of these institutions will find their way to future legislation. If we are to use RCSs successfully, it is thus necessary to discuss RCSs not just in their own particular contexts, but rather in a broader context and as the widely accepted innovation policy tools that they have become.

While the story of RCSs began in the 1970s, it was not until the 1980s that they gained notoriety. In 1983 and 1984, respectively, Congress passed the Orphan Drug Act (ODA)⁴ and the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act).⁵ Both Acts represented the culmination of intense efforts to revitalize pharmaceutical technology, and both were preceded by debates that would eventually shape health care as we know it. At the center of these debates was the balancing of two competing yet equally important public policy goals: On one hand, the goal of creating incentives for innovation in pharmaceuticals and production of socially valuable data; and on the other hand, the goal of increasing the public's access to such drugs by facilitating the approval of more affordable, generic versions of such drugs. Eventually, a solution emerged that accommodated both interests and made it possible for the industry and consumers to reach a historic compromise. Central to that compromise was the institution of a novel benefit, which was to be administered by the Food and Drug Administration (FDA), and was separate from and independent of any patents covering the regulated pharmaceutical products.⁶ It did not manifest in a direct grant of any identifiable right by the regulating agency. Rather, the benefit mandated that the agency, having used its power to approve the marketing of a regulated product, will be unable, temporarily, to do so again for competing products, thereby effectively creating a shelter from competition—an exclusivity.

²The two other articles will be dedicated to a more in-depth discussion of policy issues surrounding RCSs in light of their intersection and interchangeability with patents, and to the international dissemination of RCSs, as a legal institution, through treaties and trade agreements.

³This Article focuses on a specific brand of RCSs whose purpose is the creation of incentives for technological innovation. While it may be more accurate to denominate such RCSs as “innovation incentivizing RCSs” (or iiRCSs for short), for the sake of clarity and simplicity, this Article will consistently use the term “RCSs.” It is quite possible, however, that future discussion of RCSs in general and other brands of RCSs in particular would require a more elaborate terminology to enable distinguishing iiRCSs from other brands of RCSs that do not necessarily share the same purpose.

⁴Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended at 21 U.S.C. § 360aa–ee and scattered sections of 25, 35 and 42 U.S.C. (2012)) [hereinafter ODA].

⁵Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 35 and 42 U.S.C. (2012)).

⁶See *infra* Part III.C.

Hence, for example, under the Hatch-Waxman Act, once the FDA has approved a drug product containing a new chemical compound, it is unable to approve other products containing the same compound for a period of five years.⁷ Similarly, under the ODA, after approving a drug product for the treatment of a certain “orphan condition,” the FDA is unable to approve another drug product treating the same condition for a period of seven years.⁸

The grant of exclusive benefits by administrative agencies⁹ is not a new phenomenon. However, the benefits instituted under the ODA and Hatch-Waxman Act were different from other kinds of benefits not only in design but also in purpose, which is primarily the creation of incentives for technological innovation.¹⁰ Both the ODA and Hatch-Waxman frameworks, including their RCSs, have been considered highly successful in achieving their respective goals.¹¹ In light of these perceived successes as well as RCSs’ many

⁷ See *infra* Part III.C. Notably, the Hatch-Waxman Act included additional RCSs as well as exceptions and limitations thereof. See *id.*

⁸ See *infra* Part II.B.

⁹ For purposes of the discussion in this Article, reference to administrative agencies includes any regulatory body in the federal, state and local levels.

¹⁰ Technological innovation is:

both the development and application of a new product, process, or service. It assumes novelty in the device, the application, or both. Thus, innovation can include the use of an existing type of product in a new application or the development of a new device for an existing application. Innovation encompasses many activities, including scientific, technical, and market research; product, process, or service development; and manufacturing and marketing to the extent they support dissemination and application of the invention.

U.S. CONGRESS, OFFICE OF TECH. ASSESSMENT, INNOVATION AND COMMERCIALIZATION OF EMERGING TECHNOLOGIES 2 (1995). Although the above definition of innovation includes the process of invention, which is frequently part of research and development (R&D) processes, innovation and invention should not be confused, whereas invention is:

the act of devising or fabricating a novel device, process, or service. Invention describes the initial conception of a new product, process, or service, but not the act of putting it to use. Inventions can be protected by patents, though many inventions are not patented, and most patents are never exploited commercially.

Id.

¹¹ Ernst R. Berndt & Murray L. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation*, 18 INT’L J. ECON. BUS. 177, 198 (2011) (reporting Hatch-Waxman Act’s success in facilitating a thriving generic pharmaceuticals industry and market); Fredric J. Cohen, *Macro Trends in Pharmaceutical Innovation*, 4 NATURE REV. DRUG DISCOVERY 78, 79 (2005) (citing the “changes in federal and local laws in the 1980s” as the reason for a competitive environment of “innovate or die”); Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. PERSPECTIVE 1993, 1993 (2007) (calling the Hatch-Waxman Act a “health policy success story” for its creation of “rules under which generic pharmaceutical products could compete with brand-name products”); Martha M. Rumore, *The Hatch-Waxman Act—25 Years Later: Keeping the*

advantages over other forms of exclusivity, RCSs acquired a reputation with policymakers and stakeholders as an effective method of structuring incentives in certain regulated markets.¹² Thus, since the early 1980s, RCSs have become a popular form of exclusivity with stakeholders in such markets, and several additional RCS regimes were instituted with the similar purpose of spurring innovation in regulated areas of technology.¹³ Moreover, RCS regimes have been growing increasingly prevalent in congressional bills, international trade

Pharmaceutical Scales Balanced, PHARMACY TIMES (Aug. 15, 2009), <http://www.pharmacytimes.com/publications/supplement/2009/GenericSupplement0809/Generic-HatchWaxman-0809>, archived at <http://perma.cc/2A7W-ZBXM> (arguing that the Hatch-Waxman Act has “fulfilled its purposes” and that it “encourage[s] growth of the generic industry and provide[s] brand companies with incentives,” providing statistics in support of the argument that the Hatch-Waxman Act encourages patent challenges of brand name drugs, has increased generic prevalence in the pharmaceutical market, and has resulted in surprising investment in R&D by generic manufacturers); *see also infra* note 156 and accompanying text. *But see* CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY xiii (1998) (estimating a lower return on investment in new drugs since the Hatch-Waxman Act was passed); Aaron S. Kesselheim, *An Empirical Review of Major Legislation Affecting Drug Development: Past Experiences, Effects, and Unintended Consequences*, 89 MILBANK Q. 450, 481 (2011) (stating that the impact of at least one of the Hatch-Waxman Act’s RCSs is controversial); Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 286 (2012) (arguing that the Hatch-Waxman Act actually weakened incentives for pharmaceutical innovation). Notably, many commentators attribute innovation in the area of pharmaceuticals, at least partly, to the incentives provided by patents. *See, e.g.*, JAMES BESSEN & MICHAEL MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 13–16 (2008); Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 556 (2009). *But see* Cynthia M. Ho, *Drugged Out: How Cognitive Bias Hurts Drug Innovation*, 51 SAN DIEGO L. REV. 419, 424–26 (2014) (arguing that the role of patents in providing incentives for innovation in the area of pharmaceuticals has been exaggerated and mischaracterized).

¹²This is evidenced, for example, by the biotechnology industry’s insistence on the institution of RCSs during the legislative discussions that preceded the enactment of the Biologics Price Competition and Innovation Act (BPCIA). *See infra* notes 217 & 229.

¹³*See infra* notes 26 & 33; Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 450–61 (2012) (discussing the advantages of RCSs over patents). Advocates for RCSs point out shortcomings in the patent regime to which RCSs provide a better alternative. *Id.* at 451. For example, RCSs are less vulnerable to legal challenges than patents, thus affording RCS right-holders more certainty. *Id.* at 455 nn.161 & 163. Even the considerable investment required to gain FDA approval is often cheaper than obtaining and defending patents. *Id.* at 455 n.160.

Biologic producers have also hotly debated the optimum period during which original biologics should have exclusivity. *See* Donna M. Gitter, *Innovators and Imitators: An Analysis of Proposed Legislation Implementing an Abbreviated Approval Pathway for Follow-On Biologics in the United States*, 35 FLA. ST. U. L. REV. 555, 613–16 (2008) (reviewing some of the proposals for exclusivity periods in original biological products).

agreements, and foreign legislation over the last few years, suggesting that even more new RCS regimes will likely be instituted in the future in the United States and elsewhere.¹⁴

These developments bring to the forefront fundamental questions regarding the nature and characteristics of RCSs.¹⁵ Expanding on the discussion in *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*¹⁶ this Article seeks to (1) define and characterize RCSs in general, (2) explain the mechanics of RCSs in the context of technological innovation, (3) offer a taxonomy of the different types of RCSs instituted to date in federal legislation, and (4) provide a survey of the federal RCS regimes instituted with the purpose of creating incentives for technological innovation. In so doing, this Article seeks to contribute to laying the groundwork to facilitate a more robust discussion of RCSs.

Part II of this Article defines RCSs, provides a general background about them, and explains why the new name proposed here, “regulatory competitive shelters,” is more fitting than previously proposed names in describing these legal institutions. Part II also offers an explanation of the way in which RCSs work in the context of technological innovation. It then suggests a nomenclature and taxonomy of the different kinds of RCSs instituted to date in the United States. Part III provides a review of federal RCS regimes instituted

¹⁴ See, e.g., the numerous RCS regimes proposed during the discussions preceding the enactment of BPCIA, *infra* note 227; the RCS regime under the GAIN Act, *infra* Part III.H; and the additional regime proposed under the MODDERN Cures Act bill, *infra* note 244; see also Rebecca S. Eisenberg, *Data Secrecy in the Age of Regulatory Exclusivity*, in *THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH* 467, 472–73, 491 (Rochelle C. Dreyfuss & Katherine J. Strandburg eds., 2011) [hereinafter Eisenberg 2011]; Rebecca S. Eisenberg, *Patents and Regulatory Exclusivity*, in *OXFORD HANDBOOK ON THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY* 167, 188 (P. Danzon & S. Nicholson eds., 2012) [hereinafter Eisenberg 2012]; John R. Thomas, *Toward a Theory of Regulatory Exclusivities*, in *PATENT LAW IN GLOBAL PERSPECTIVE* 345, 346, 370–75 (Ruth L. Okediji & Margo A. Bagley eds., 2014) (surveying proposals for the institution of additional RCS regimes and anticipating the establishment of additional RCS regimes in the future).

¹⁵ Legal literature has mostly addressed RCSs in the specific contexts of the particular legislative frameworks in which they play a role, but, with a few exceptions, has not dedicated much attention to them as such. See generally Eisenberg 2012, *supra* note 14; C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 *ANTITRUST L.J.* 947 (2011); Vincent J. Roth, *Will FDA Data Exclusivity Make Biologic Patents Passé?*, 29 *SANTA CLARA COMPUTER & HIGH TECH. L.J.* 249 (2013). But see Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 *MICH. TELECOMM. & TECH. L. REV.* 345 (2007) [hereinafter Eisenberg 2007] (generally characterizing the exclusivities administered by the FDA in the context of pharmaceutical technologies as “pseudo-patents”).

¹⁶ Heled, *supra* note 13, at 424 (comparing RCSs and patents in the context of biological pharmaceuticals, highlighting the advantages of RCSs over patents in that context and recommending the suspension of enforceability of patent rights covering such pharmaceutical products where RCSs are in place).

for the purpose of creating incentives for technological innovation¹⁷ while highlighting some of the common motifs described in Part II. Part IV tackles the question of why almost all RCS regimes instituted to date are administered by the FDA and what this fact may say about the general applicability of RCSs as a mechanism for spurring technological innovation. This Article concludes with outstanding questions regarding RCS regimes that merit further attention.

II. REGULATORY COMPETITIVE SHELTERS—AN EXPOSITION

A. *Regulatory Competitive Shelters—Definition and Characterization*

Broadly defined, regulatory competitive shelters are competitive advantages resulting from statutory bars on regulatory action where such action is otherwise mandated and would have taken place but for the triggering of the bar. Thus, RCSs are the result of an administrative agency's inability to take certain regulatory action that, had such action been taken, would have paved the way for competition in a certain product or market. The agency's non-action¹⁸ (resulting from the statutory bar) creates an impediment to competition in a market or product regulated by the agency, thereby effectively sheltering the beneficiary of the earlier regulatory action from potential competition, typically by instigating exclusivity in the market or product.¹⁹ Hence, RCSs effectuate a competitive advantage in the relevant market or product and, often, even de facto monopoly status with respect to a particular product. Put metaphorically, regulatory competitive shelters are an exclusive "right of entry" into a regulated "territory," wherein the right of entry is conferred by a government gatekeeper on one or a few individuals, thereby making the "territory" the sole domain of such individuals for a predetermined period of time, after which such "rights of entry" may be given to others as well.²⁰

¹⁷ As a legislative phenomenon, RCSs are not limited to the federal level. *See, e.g.*, *Chem. Producers & Distribs. Ass'n v. Helliker*, 463 F.3d 871, 874–75 (9th Cir. 2006) (describing an RCS regime instituted by the state of California).

¹⁸ I use the term "non-action" rather than "inaction" so as to avoid the implication that agency action is appropriate and ought to be expected. However, there may be cases in which agency non-action in the context of RCSs may actually be "agency inaction"—a topic of substantial case law involving the review of agency's discretion as to whether or not to take regulatory action. *See, e.g.*, *Heckler v. Chaney*, 470 U.S. 821, 831–35 (1985) (addressing the issue of reviewability of agency inaction).

¹⁹ As explained by Professor Rebecca Eisenberg in the context of RCSs administered by the FDA under the Hatch-Waxman Act, "[i]n effect, these provisions amount to FDA-administered proprietary rights in regulatory data, awarded to encourage particular kinds of innovation in drug development rather than to protect consumers from unsafe or ineffective drugs. The practical effect is to defer generic competition, even without patent protection." Eisenberg 2007, *supra* note 15, at 360.

²⁰ *Cf.* Bruce S. Manheim Jr. et al., 'Follow-On Biologics': Ensuring Continued Innovation in the Biotechnology Industry, 25 HEALTH AFF. 394, 394 (2006) (defining

RCSs are different from most other kinds of administratively created exclusivities²¹ in the manner by which they are conferred upon the beneficiary. Whereas administratively created exclusivities are, typically, the result of an affirmative act of *direct* grant of the exclusivity by an administrative agency, the benefits conveyed by RCSs are usually not “granted” in the regular sense, but are rather byproducts of a triggering event that strips the agency of the power to partake in certain regulatory actions.²² Put more simply, RCSs do not necessitate a formal “nod” to validate their existence and confer their benefits. This is not to say that agency acknowledgement of the existence of an RCS or a beneficiary status thereof is at odds with the nature and purpose of RCSs. Rather, the benefits conferred under RCS regimes are byproducts of an *inability* of potential competitors to partake in a regulated activity, and nothing more. While the author is not aware of any RCS regimes in which the onset of an RCS is *not* automatically triggered, this characteristic does not seem to be a *sine qua non* of RCSs as it is possible to envision RCS regimes that would require official confirmation from the relevant administrative agency for the RCS to actually take effect. To illustrate: the FDA need not *grant* to a manufacturer of an orphan drug the seven-year exclusivity status in the drug as mandated under the Orphan Drug Act in order for this particular RCS to take effect; rather, the seven-year RCS is triggered *automatically* by the approval of the drug for an orphan condition.²³ In other words, RCSs under the Orphan Drug Act are not conferred in the same sense that the United States Patent and Trademark Office (USPTO) grants patents to applicants (including the issuance of a certificate and publishing the patent in official records). Rather, after the approval of a drug for an orphan condition, the FDA’s only obligation

“statutory exclusivity” as “the period of time in which the FDA is barred from approving a follow-on product”).

²¹ See *infra* notes 68–72 and accompanying text for examples of such exclusivities.

²² Examples of exclusivities that are the result of direct grants are patents and trademarks whose conferral requires an affirmative act of issuance and registration by the U.S. Patent and Trademark Office (USPTO). RCSs, by contrast, are the result of a triggering event, which may or may not directly pertain to the benefit conferred by the RCS. In other words, the triggering event that strips the administrative agency of its power to take regulatory action, thereby creating the benefit that is the subject of the RCS, may be seemingly unrelated to the RCS.

Notably, in some cases, the RCS’s triggering event may be closely related to the RCS itself. Examples are: (1) the designation of a certain medical condition as a rare disease as a precondition for the triggering of the seven-year market exclusivity RCS under the Orphan Drug Act; and (2) the need for FDA’s finding of satisfactory fulfillment of a clinical studies request pertaining to pediatric populations, which is necessary to trigger the six-month pediatric exclusivity RCS. See *infra* notes 146 & 198, respectively, and accompanying text. However, even in these cases, the designation and finding of satisfactory fulfillment by the administrative agency, while closely related to the context of their respective RCSs, is not the same as direct grant of the exclusivity.

²³ See *infra* Part III.B.

is to refrain from approving follow-on (a.k.a. “me too”) versions of that drug for the same conditions for a period of seven years.²⁴

For the same reason that they do not require an affirmative act of formal grant, RCSs typically confer no specific actionable right on their beneficiaries.²⁵ This does not mean that an applicant for regulatory approval of a product whose approval triggers an RCS cannot reasonably rely on the benefits that the applicant expects to gain from the onset of that RCS. Rather, RCSs do not involve any right that can be identified by name or which may create adversity between the RCS’s beneficiary and a subsequent applicant. This, in turn, does not harm RCS-beneficiaries. One of the most important aspects of RCSs is that they are “automatically enforced” by their administering agency.

As mentioned earlier, RCSs are the result of *non-action* by an agency, which is due to a temporary loss of the agency’s ability to use its powers to benefit applicants subsequent to the RCS-beneficiary. Stated differently, the enforcement of RCSs is a result of the regulatory shelter created by the administrative agency and, thus, requires no enforcement action per se on the part of RCS-beneficiaries.²⁶ Hence, the benefits arising from RCSs are *incidental* to the bar imposed on the relevant administering agency and typically do not require enforcement action per se by the beneficiary. By the same token, beneficiaries of RCSs are not in a position to “enforce” their RCSs on potential third party competitors, although in some cases RCS-beneficiaries may petition the administering agency to take regulatory action against third parties.²⁷

RCSs may serve to achieve a variety of conceivable purposes in different regulatory contexts and settings.²⁸ This Article, however, will focus on

²⁴ *Id.*

²⁵ In this regard, RCSs are different, for example, from patents that grant their recipient the ability to exclude others from practicing the invention as claimed under the patent. See 35 U.S.C. § 271(a) (2012).

²⁶ See Elizabeth H. Dickinson, *FDA’s Role in Making Exclusivity Determinations*, 54 FOOD & DRUG L.J. 195, 195 (1999) (“FDA enforces exclusivity protections; they are not asserted independently in the same type of proceedings in which patent rights are asserted.”); Joyce Wing Yan Tam, Note, *Biologics Revolution: The Intersection of Biotechnology, Patent Law, and Pharmaceutical Regulation*, 98 GEO. L.J. 535, 553 (2010) (“Marketing exclusivities are particularly powerful This perfect monopoly protection is automatic and does not require the entity holding the [product] exclusivity to act—a sharp contrast to patent rights, which are *only* enforced when the patent holder prevails in a legal action.”); ALEX M. BRILL, PROPER DURATION OF DATA EXCLUSIVITY FOR GENERIC BIOLOGICS: A CRITIQUE 6 (2008), available at http://www.matrixglobaladvisors.com/storage/mga-studies/Brill_Exclusivity_in_Biogenics.pdf, archived at <http://perma.cc/S825-8DVQ> (“Data exclusivity is a definitive monopoly and a government grant, as it allows the innovator’s data to be protected without challenge.”).

²⁷ See, e.g., 21 C.F.R. § 10.30 (2014) (providing a mechanism known as “citizen petition” to request the FDA to take regulatory action).

²⁸ For example, RCSs may conceivably serve to promote private investment in infrastructure, compliance with voluntary standards recommended (but not mandated) by

describing and characterizing the important brand of RCSs instituted to create incentives for the development of new technology and make it available for use by the public.²⁹ Such RCSs are highly similar to patents. This similarity is not coincidental, as RCSs were first created in response to perceived needs that were unmet under patent law.³⁰ However, RCSs are different from patents in the way they make the technological innovation that they “shelter” available to the public.

Patents are explicitly designed to disclose relevant information regarding the technology to the public (in the specification portion of the patent document) so as to make it possible for members of the public to make and use the invention.³¹ RCSs, however, make the technologies they cover available to the public in three important ways. First, RCSs provide economic incentives, in the form of the competitive advantages to disseminate approved regulated technologies, thereby making them available to the public.³² Second, as a byproduct of the grant of regulatory approval, RCSs signal that the societal value of the technologies subject to RCS was evaluated by the administering

an administrative agency, etc. *See also* Thomas, *supra* note 14, at 370 (“[R]egulatory exclusivities could in theory be applied to virtually any regulated product.”).

²⁹ According to Professor John Thomas, the purpose of RCSs, including many of those discussed in this Article, must not be viewed as the incentivizing of innovation but rather as the production of socially valuable data necessary for expensive regulatory processes. *See* Thomas, *supra* note 14, at 346. Thomas makes a compelling argument that RCSs “should be framed as *sui generis* rights that complement, rather than supplement the patent system” and that “[t]he account of [RCSs] as a patent-like innovation promoter has both shortcomings and descriptive flaws.” *Id.* at 346, 360–62. Nevertheless, he acknowledges that at least some RCS regimes break away from the traditional role of RCS regimes as incentives to generate data as they aim to supplement patents and even replace them altogether. *See id.* at 363, 375 (discussing the Biologics Price Competition and Innovation Act of 2009 and the MODDERN Cures Act).

Without addressing all of Professor Thomas’s many compelling arguments, which exceeds the scope of this Article, as a practical matter, the incentivizing of technological innovation and the production of socially valuable data are not mutually exclusive and may well coincide in the context of RCSs. Indeed, as mentioned earlier, RCSs may serve to promote a variety of purposes and social goals. Thus, while Professor Thomas’s position regarding the purpose of RCSs reflects good public policy, the characterization of RCSs exclusively as a means for production of socially valuable data does not seem to necessarily follow.

³⁰ *See* discussion, *infra* Parts III.A–C.

³¹ This “trait” of patents is embodied in patent law’s enablement and written description requirements. *See* 35 U.S.C. § 112(a) (2012) (“The [patent] specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same . . .”).

³² By contrast, patents do not necessarily provide incentives to make patented products available to the public. Benjamin Roin observed and analyzed this difference between patents and RCSs in the context of the pharmaceutical industry. *See* Roin, *supra* note 11, at 555–56 (lamenting the non-pursuit of development of potentially beneficial drugs due to a lack of patent protection for the resulting product).

agency and found to be satisfactory based on the regulatory requirements imposed by the administering agency.³³ In other words, the onset of an RCS triggered by the approval of a regulated technology serves as an indirect signal to the public that the information submitted to the reviewing agency in connection with the application for the marketing of the technology was sufficient to meet the agency's merit standards (or not, in the case of a rejection).³⁴ And third, in many cases RCS regimes provide a way for manufacturers of follow-on products to rely on data regarding the technology that is the subject of the RCS, which was submitted to the administering agency in connection with the approval of the original product, when these manufacturers seek approval for their follow-on products.³⁵ In so doing, RCS regimes facilitate not only efficiencies in the production and utilization of data necessary for the regulatory approval process by the administering agency, but also the widespread dissemination of the technology upon expiration of the RCS period.

B. *The Mechanics of Regulatory Competitive Shelters*

The purpose of all RCSs is to provide *specifically tailored* incentives intended to spur technological innovation in select areas in which such incentives are deemed necessary.³⁶ Instituting an RCS regime requires an agency to administer the regime and function as a gatekeeper whose actions would instigate the creation of the RCSs. The role of such administrative agencies in RCS regimes is, thus, twofold: (1) they serve as “examining” bodies in charge of evaluating the merit of relevant technologies; and (2) they function as administrators of the relevant exclusivities.

The structure of basic RCS regimes may be illustrated as follows: (1) a product manufacturer (M)³⁷ invests resources developing a technology that may come to fruition in a product (P); (2) M then submits an application for marketing approval of P to the relevant administrative agency (AA) in charge of regulating that area of technology or type of product; (3) AA reviews the application to determine whether P meets its merit standards, usually by evaluating P's safety and efficacy; (4) if P is found to meet AA's regulatory approval criteria, AA grants M marketing approval for P; (5) AA then refrains

³³ By contrast, patents do not reflect the direct social value of the patented inventions and are merely reflective of the novelty, non-obviousness and potential utility of the patented invention. *See id.* at 536–37.

³⁴ Notably, prominent scholars have argued that in the case of pharmaceutical technologies, the information submitted to the administrative agency should also be made available to the public. *See infra* notes 42–45 and accompanying text.

³⁵ *See infra* notes 39–45 and accompanying text.

³⁶ *See infra* Part III.

³⁷ For simplicity, in this Article I will generally refer to the parties involved in the R&D, application for marketing approval, making and distributing of a product as that product's “manufacturer.”

from taking certain regulatory actions with respect to subsequent applications, (e.g., it does not accept or approve applications for products similar or identical to P (“follow-on products”) for a certain amount of time (T) as proscribed under the RCS-instituting statute, thereby fully or partially sheltering M from competition in P);³⁸ (6) using its competitive advantage, M is able to sell P at a high profit margin, thereby recouping its investment in research and development (R&D) and regulatory costs; (7) upon the lapse of T, AA resumes its previously-barred regulatory action (e.g., begins accepting or approving applications for follow-on versions of P).

This quid pro quo may be illustrated as follows:

Table 1: *Basic RCS Regime*

M	Quid Pro Quo	AA/the Public
Gives	Investment in technological innovation resulting in the development, approval, and marketing of P	Receives
Receives	1. Examination of application for marketing of P 2. Approval of application for marketing of P and opportunity to enter the market 3. Sheltering from competition in P via RCS during T (resulting in sale of P at a high profit margin)	Gives

In addition to this basic RCS regime structure, some RCS regimes include, as an essential component, the authorization of the relevant administrative agency to use R&D information previously submitted to the agency by applicants in reviewing applications for follow-on products.³⁹ Such authorization is typically a component of RCS regimes in which R&D information is required by the administrative agency in order to consider and approve technological products for marketing. In such regimes, the submitted information also serves an important function: facilitating approval of follow-on products without requiring the re-submission of similar R&D information

³⁸ Such sheltering from competition may be more or less comprehensive, depending on the particular RCS regime and its underlying public policy goals. Compare the strong RCS afforded under the Orphan Drug Act and the relatively weak shelter from competition in pesticides under FIFRA. *See infra* Parts III.B & III.A, respectively.

³⁹ *See, e.g.*, 21 U.S.C. § 355(j)(1) (2012) (in small molecule drugs); 21 U.S.C. § 360j(h)(4)(A) (2012) (in medical devices); 42 U.S.C. § 262(k)(3) (2012) (in biologics); 21 U.S.C. § 360b(n) (2012) (in new animal drugs); 7 U.S.C. § 136a(c)(1)(f)(iv) (2012) (in pesticides). Notably, the administrative agency may need to refer to information submitted by an applicant not only in connection with reviewing applications for follow-on products, but also in other situations that may require further review of such information (e.g., in evaluating new information collected in post-marketing studies of the regulated product).

by the follow-on applicant, so as to avoid societal waste.⁴⁰ This, in turn, makes the development price of such follow-on products cheaper, thereby making these products more widely accessible.

The use of an initial applicant's R&D information by an administrative agency is known as "reference" and is often the *raison d'être* of the "pact" instituted under certain RCS regimes between the original product manufacturer and the public (as "represented" by the administrative agency).⁴¹ Importantly, in the United States, the information submitted to administrative agencies (including, in many cases, clinical data) for the purpose of evaluating technologies is generally considered proprietary.⁴² Accordingly, such information is held in confidence by administrative agencies and usually is not shared directly with subsequent follow-on applicants or the general public.⁴³

⁴⁰ See *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1014–15 (1984) (explaining the rationale behind data sharing).

⁴¹ See Gitter, *supra* note 13, at 586 (acknowledging the goal of fostering a competitive market for safe biological pharmaceuticals while continuing to provide incentives for innovation); Bryan A. Liang, *Regulating Follow-On Biologics*, 44 HARV. J. ON LEGIS. 363, 388 (2007) (understanding the Hatch-Waxman Act to create a balance between the original manufacturer's incentive to innovate and the goal of increasing the number of affordable and safe generic drugs available to the public).

Thus, in RCS regimes that include this component the administrative agency plays an additional (third) role, namely that of a "trustee" or "escrowee" holding the information submitted in confidence for future reference, as necessary, in the approval of applications for marketing of follow-on products.

⁴² See, e.g., in the context of FDA law, 21 U.S.C. § 331(j) (2012). This is, however, not the case in other countries, where such data is not kept in confidence, but rather is available to the public.

RCS regimes that facilitate a deposit of information, which may later be referenced by the administrative agency in reviewing applications for follow-on products, are reminiscent of trade secret regimes in several ways: (1) like trade secret regimes, they seek to create incentives for technological invention and innovation; (2) except for some information about the product itself, none of the information pertaining to know-how gained during its development is disclosed to the public, which enables the preservation of the proprietary value of this information; and (3) the barrier formed by the RCS regime—like with trade secrets—is not necessarily insurmountable and may not apply to independent development of the same or a similar product. To clarify this point: just like independent development of a trade secret does not constitute misappropriation, RCSs do not necessarily pose a regulatory impediment to the review and approval of applications for competing products as such (although they certainly might do that, depending on the language of the statutory provision establishing the specific RCS).

⁴³ Christine D. Galbraith, *Dying to Know: A Demand for Genuine Public Access to Clinical Trial Results Data*, 78 MISS. L.J. 705, 720 (2009) (noting the FDA's treatment of drug data as proprietary). Data that is classifiable as a trade secret or confidential commercial information usually cannot be disclosed to the general public without the applicant's authorization—in fact, the Trade Secrets Act criminalizes disclosure of this information by an FDA employee. 18 U.S.C. § 1905 (2012). Federal regulation broadly defines trade secrets and confidential commercial information. See 21 C.F.R. § 20.61(a) (2004) (defining trade secret as consisting of "any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of

Rather, in “referring” to such information as part of the approval process of follow-on products, administrative agencies do not disclose the referenced information to the subsequent applicant but only use it internally in the evaluation of subsequent applications for follow-on products.⁴⁴ Keeping such information in confidence, however, does not appear to be a crucial element of RCS regimes and may even be viewed as deadweight loss accompanying RCS regimes, which do not require disclosure of R&D information regarding the approved product. Indeed, as several prominent scholars have argued, keeping information submitted to an administrative agency in support of a regulatory filing in confidence is mostly, if not always, unjustified as a means of creating incentives for innovation and detrimental from a public policy perspective.⁴⁵

In RCS regimes that include such a “reference” component, the RCSs are typically crafted in the first place so as to provide sufficient competitive advantage to compensate the RCS-beneficiary (which submitted the information) for the later loss associated with the use of its proprietary information in the approval of third-party applications. The quid pro quo arrangements embodied in these types of RCS regimes, which I will refer to as “RCS Pacts,” may be summarized as follows: (1) the original product manufacturer (M1) invests resources in R&D of a technology that may come to fruition in a product (P1); (2) M1 then submits an application for marketing approval of P1 (including relevant information gathered during P1’s development) to the administrative agency (AA) in charge of regulating that area of technology or type of product; (3) AA reviews the application, including the information (D) submitted in support thereof, to determine whether P1 meets its merit standards (usually by evaluating P1’s safety and efficacy); (4) if P1 is found to meet AA’s regulatory approval criteria, AA

trade commodities and that can be said to be the end product of either innovation or substantial effort.”); 21 C.F.R. § 20.61(b) (2014) (defining confidential commercial information as “valuable data or information which is used in one’s business and is of a type customarily held in strict confidence . . . by the person to whom it belongs.”).

⁴⁴ Such agency use of arguably proprietary information has been justified as one of “the burdens we all must bear in exchange for ‘the advantage of living and doing business in a civilized community.’” See *Ruckelshaus*, 467 U.S. at 1007 (citation omitted) (addressing the constitutionality of agency use of proprietary information in light of the Fifth Amendment).

⁴⁵ See Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL’Y L. & ETHICS 717, 720 (2005) (arguing that trade secrecy in clinical trials information truncates the social value of the information and is therefore problematic and proposing combining exclusive rights in product markets with public disclosure of data from clinical trials); Eisenberg 2011, *supra* note 14, at 468–73, 486; Eisenberg 2007, *supra* note 15, at 380–84; Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPS Agreement*, 45 HARV. INT’L L.J. 443, 448 (2004); Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1, 48–49 (2009); Marc A. Rodwin & John D. Abramson, *Clinical Trial Data as a Public Good*, 308 JAMA 871, 871 (2012).

grants M1 marketing approval for P1 while keeping D for future reference when deciding on applications for marketing-approval of follow-on versions of P1 (P2s); (5) AA then refrains from referring to D or accepting or approving applications for P2s for a certain amount of time (T) as proscribed under the RCS-instituting statute, thereby sheltering M1 from competition in P1; (6) using its competitive advantage, M1 is able to sell P1 at a high profit margin, thereby recouping its investment (in R&D and regulatory costs); (7) upon the expiration of T, AA begins accepting or approving applications for P2s, whereas such applications may call for AA to refer to D in conducting its review;⁴⁶ (8) AA approves applications for P2s, thereby ceasing its sheltering of M1 and opening the market in P1 to competition between M1 and follow-on product manufacturers (M2s) whose expenses in developing their P2s were much lower than those of M1 in developing P1; (9) in order to compete effectively, M2s offer their P2s for a lower price than that for which P1 is sold, thereby facilitating a drop in the price of P1 and the product in general;⁴⁷ and (10) the resulting decrease in the product's price makes it accessible to a broader consumer base.

⁴⁶ See *supra* notes 43–44 and accompanying text.

⁴⁷ The Federal Trade Commission (FTC) estimates that when a M1's competitive advantage is maintained by patents, about one year after the removal of such patents (through expiration or invalidation) and market entry of a generic, on average, P2s take over ninety percent of P1's unit sales and sell for fifteen percent of the original price of P1. See FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010), available at <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>, archived at <http://perma.cc/933E-X5XX>.

The quid pro quo of RCS Pacts is illustrated in the following table:

Table 2: *RCS Regime with a “Reference” Component*

M	Quid Pro Quo	AA/the Public
Gives	1. Investment in technological innovation resulting in the development, approval, and marketing of P1 2. Submission of D, which may be referred to in the approval of P2s after T (resulting in P2s sold for lower prices, thereby increasing accessibility)	Receives
Receives	1. Examination of application (including D) for marketing of P 2. Approval of application for marketing of P and opportunity to enter the market 3. Sheltering from competition in P1 via RCS during T (resulting in sale of P1 at a high profit margin)	Gives

Importantly, all of the RCS regimes instituted to date essentially bar the relevant administrative agency from taking at least one of the following three regulatory actions during T: (1) accepting applications for follow-on products, (2) approving applications for follow-on products, and (3) referring to data submitted to the agency in connection with an earlier application during the review and evaluation of subsequent applications. However, RCSs do not necessarily have to be limited to these particular regulatory impediments. Indeed, hypothetically, RCSs may pertain to *any* regulatory action that an agency is authorized to take. For example, if administrative agency AA is authorized to issue advisory opinions, an RCS may prohibit AA from issuing such opinions for a certain period of time, so as to benefit M1. Similarly, if AA is required to provide funding for certain activities, an RCS may prohibit AA from providing such funding for a certain period of time subsequent to the grant of such funding to M1. Clearly, one could envision many more kinds of RCSs than those that exist under current legislation. As explained in Part III of this Article, RCS Pacts have been a strong impetus to the institution of RCS regimes and are an important element of such regimes.

C. A Taxonomy of Regulatory Competitive Shelters

The scope of protection (or sheltering) conferred under each RCS regime depends on the legislation that defines the powers of the administrative agency

administering that RCS.⁴⁸ Accordingly, the actual bundle of rights that comes along with each RCS depends on the specific definition and context of the RCS as well as on the administering agency's understanding of the RCS's instituting statute. In other words, the protection conferred under each RCS is directly related to what the administrative agency administering the RCS regime is able to "shelter" the RCS holder from, which in turn depends on the powers that the agency has under the relevant legislation and generally.⁴⁹ For example, withholding FDA approval for marketing a follow-on version of pharmaceutical drug "X" means that, in accordance with FDA legislation, manufacturers of follow-on versions of X are not allowed to introduce such versions into interstate commerce⁵⁰ or import it into the United States without prior FDA approval.⁵¹ This, in turn, potentially confers on the original manufacturer of X a shelter from competing sales of follow-on versions of X and their importation into the United States. These shelters are different, for example, from the rights conferred under the Patent Act to exclude others from making, using, selling, offering to sell and importing into the United States the patented invention.⁵² Thus, the RCS pertaining to X under FDA legislation would not necessarily shelter the original drug manufacturer from competing use, offering for sale, or making of X.⁵³

Despite the fact that different RCSs may vary in the type and scope of the benefits and rights that they confer, all RCSs are, by definition, geared towards limiting competition in some way. In that vein, all of the currently-instituted RCSs may be characterized as falling into one or more of the subgroups described in the following sections.

1. *Market Exclusivity*

This group of RCSs is defined by a period during which potential competitors (M2s) are not allowed to enter the market for a certain regulated product (P) with their own version of that product.⁵⁴ Market exclusivity is achieved by a prohibition imposed on an administrative agency (AA) to accept or approve applications for comparable or identical products (P2s) for the duration of the exclusivity period. Market exclusivity is typically a strong RCS

⁴⁸ As explained in the previous subsection, the type and scope of RCSs depends on the regulatory action that the relevant administrative agency is statutorily prohibited to take for the duration of the RCS. *See supra* Part II.B.

⁴⁹ *Id.*

⁵⁰ *See* 21 U.S.C. §§ 331(d), 355(j) (2012).

⁵¹ 21 U.S.C. § 331(aa).

⁵² 35 U.S.C. § 271(a) (2012). A notable exception to this rule is the exclusion of partaking in such acts "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1).

⁵³ *See* 21 U.S.C. § 331 (detailing food and drug manufacturing and sale prohibitions).

⁵⁴ *See* Gitter, *supra* note 13, at 573 n.113 (defining "market exclusivity").

and confers on its beneficiary (M1) the ability to sell the product (P1) at a high profit margin. Nonetheless, it is important to note that market exclusivities do not guarantee market power⁵⁵ to their beneficiaries. Indeed, there is currently no example of a market exclusivity, which has by its definition conferred such complete reign over a particular market so as to bar competition in that market under *any* circumstances.⁵⁶ Accordingly, for example, a seven-year market exclusivity under the Orphan Drug Act does not preclude potential competitors from developing their own drug for a certain rare disease and entering the market for treatment of that rare disease prior to the lapse of the seven-year market exclusivity period, provided that their drug is not identical to (or a follow-on version of) the drug that is subject to the market exclusivity.⁵⁷

2. Data Exclusivity

This group of RCSs is defined by a period during which subsequent applicants (M2s) may not rely on or seek reference to information (D) previously submitted to an administrative agency (AA) in support of an application for marketing approval of a previously-approved product (P1), for the purpose of approving their own follow-on version of that product (P2).⁵⁸ Data exclusivity is achieved by a prohibition preventing the AA holding D from referring to such information in its review and approval of later applications for marketing approval of P2s for the duration of the exclusivity

⁵⁵ Market power is defined as “[t]he ability to reduce output and raise prices above the competitive level—specifically, above marginal cost—for a sustained period, and to make a profit by doing so.” BLACK’S LAW DICTIONARY 1058 (9th ed. 2009). In antitrust law, a large amount of market power may constitute monopoly power. *Id.* Further, “[i]n economic terms, market power is the ability to raise prices without a total loss of sales; without market power, consumers shop around to find a rival offering a better deal.” *Id.* (quoting from 54 AM. JUR. 2D *Monopolies, Restraints of Trade, and Unfair Trade Practices* § 49, at 110 n.87 (1996)).

⁵⁶ Nevertheless (potential antitrust law issues aside), the institution of such strong RCSs is not unthinkable where the public policy goal at the heart of the RCS regime would necessitate particularly strong incentives. In the context of pharmaceuticals, for example, such an RCS may work its effect by barring the FDA from approving any drugs for a certain condition or disease for the period of the RCS subsequent to the approval of a first product to enter the market. Under such a hypothetical RCS regime, an original manufacturer of a drug for such a condition or disease would be sheltered from *any* competition by *any* maker of a potentially competing drug, regardless of whether the potentially competing drug is a follow-on version of the original drug, even if the potentially competing product is proven safer or more effective than the original drug.

⁵⁷ See Richard Y. Cheung et al., *Orphan Drug Policies: Implications for the United States, Canada, and Developing Countries*, 12 HEALTH L.J. 183, 185 (2004).

⁵⁸ See LAURENCE J. KOTLIKOFF, STIMULATING INNOVATION IN THE BIOLOGICS INDUSTRY: A BALANCED APPROACH TO MARKETING EXCLUSIVITY 3, 5 (2008), available at http://www.kotlikoff.net/sites/default/files/Kotlikoff_Innovation_in_Biologics_21.pdf, archived at <http://perma.cc/3TSM-8ZNG> (discussing the terms data and market exclusivities).

period (T). Data exclusivities, however, do not preclude subsequent applicants, who do not seek to rely on data submitted by P1s, from submitting their own, independently developed data in support of applications for the approval of their own products that may compete, once approved, with P1.⁵⁹ Rather, data exclusivities operate by maintaining the barriers to market entry that are associated with requirements for data as a pre-condition for the administrative agency's approval of a product for marketing.⁶⁰ As discussed earlier,⁶¹ the term "data exclusivity" has been defined rather loosely in the literature discussing the various RCS regimes.⁶² Still, the resemblances borne by all data exclusivities to other RCSs should not lead to the common misperception that all RCSs are data exclusivities.

3. *Generic Exclusivity*

This group of RCSs is defined by a subtype of market exclusivity granted to manufacturers (M2s) of approved follow-on products (P2s) during which an administrative agency (AA) will not approve applications subsequent to a first approved follow-on application, where such applications are submitted by even later applicants (M3s) who seek approval for the marketing of their own version of the follow-on product (P3s).⁶³ Generic exclusivities are usually meant to serve as an incentive for the entry of follow-on products into markets that are characterized by being monopolistic or where one manufacturer (typically of the original or reference product) has market power. Generic exclusivities tend to create duopolistic markets in which the original product manufacturer and the generic exclusivity beneficiary—the manufacturer of the follow-on product—both have market power.⁶⁴ The term "generic exclusivity"

⁵⁹ See David E. Adelman & Christopher M. Holman, *Misplaced Fears in the Legislative Battle over Affordable Biotech Drugs*, 50 IDEA 565, 569 (2010). Submission of independently gathered data by subsequent applicants is, however, usually discouraged by the fact that such subsequent applicants are typically unable to secure any kind of exclusivity—patent or RCS—in their follow-on products that would enable them to recuperate the costs associated with the data gathering.

⁶⁰ *Id.*

⁶¹ See *infra* Part II.D.

⁶² See, e.g., Gitter, *supra* note 13, at 572 n.108 (referring to "data exclusivity" as the period during which the FDA cannot approve an Abbreviated New Drug Application (ANDA) for a generic drug); Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 189 (1999) (explaining that a period of exclusivity during which a generic version of a drug cannot be approved is generally referred to as "data exclusivity").

⁶³ To further clarify: generic exclusivity is a period during which AA will not approve P3s subsequent to the approval of a P2, whereas M3s who submit such P3 applications—like M2 who submitted the application for P2 before them—seek to rely on D submitted by M1 in connection with P1.

⁶⁴ See Gitter, *supra* note 13, at 573 (noting that during the 180-day period the generic drug "shares duopoly prices with the Brand-name drug").

is often used in the legal literature in connection with the RCS regimes administered by the FDA pertaining to pharmaceutical products.⁶⁵

Although all of the RCSs instituted to date fall into one of these three exclusivity types, it is important to recognize that there could be RCSs that do not fall under any of them. By their definition, RCSs could, hypothetically, pertain to *any* statutorily mandated action by *any* administrative agency. Thus, one could envision RCSs pertaining to an administrative agency's ability to exempt a potential beneficiary from a certain aspect of its regulation, grant it a special tax status, or provide it with government funding (while refraining from doing the same thing for its competitors), issue an agency opinion or guidance document per the request of a particular beneficiary (again, while refraining from taking the same action in response to requests by others), and more. Viewed in this light, it becomes apparent that market exclusivity, data exclusivity, and generic exclusivity are but a few kinds of many possible RCSs.

D. Regulatory Competitive Shelters: Nomenclature

There is much confusion and incoherence within the literature discussing RCSs with respect to the name and terms used to describe them as a legal and regulatory phenomenon.⁶⁶ Needless to say, this inconsistency is unhelpful and, at times, even harmful for the discussion of RCSs. For this reason as well as to steer the discussion away from unnecessary controversy regarding the correct meaning of this term or another, a new name—regulatory competitive shelters—is proposed herein for this regulatory institution. The name “regulatory competitive shelters” also better describes the type of exclusivities and exclusivity regimes discussed in this Article than the most commonly used terms “regulatory exclusivities,” “statutory exclusivities,” and “data exclusivities.”⁶⁷ The terms “regulatory exclusivities” and “statutory exclusivities,” for one, do not draw a distinction between the various different kinds of exclusivities administered by administrative agencies and cannot serve to distinguish, for example, between patents,⁶⁸ monopoly rights granted to utility companies in certain jurisdictions,⁶⁹ plant variety protection,⁷⁰

⁶⁵ See, e.g., Hemphill & Lemley, *supra* note 15, at 948.

⁶⁶ See Thomas, *supra* note 14, at 349.

⁶⁷ See, e.g., Heled, *supra* note 13, at 419 (“Patents vs. Statutory Exclusivities . . .”); Brian F. McMahon, *The Biologics Price Competition and Innovation Act of 2009: Legislative Imprudence, Patent Devaluation, and the False Start of A Multi-Billion Dollar Industry*, 100 KY. L.J. 635, 641 (2012) (using the term “regulatory exclusivity”); Roth, *supra* note 15, at 277–78; John R. Thomas, *Into a Silver Age: U.S. Patent Law 1992–2012*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 525, 540–42 (2013) (discussing “the rise of regulatory exclusivities”).

⁶⁸ Patents are administered under 35 U.S.C §§ 100–130 (2012).

⁶⁹ For example, the Georgia Territorial Electric Service Act provides a mechanism for assigning geographical monopolies to electrical suppliers. GA. CODE ANN. §§ 46-3-2, 46-3-4 (2004). Another noteworthy example is the entitlement of the United States Postal

trademarks,⁷¹ and the new chemical entity exclusivity instituted under the Hatch-Waxman Act.⁷² Hence, these terms do not point at the kind of exclusivities discussed in this Article with sufficient specificity and are, arguably, generic to any kind of exclusivity mandated by a statute or administered by a regulatory body. Conversely, the term “regulatory competitive shelter” is by its very name specific to the unique circumstances and attributes characterizing the exclusivities discussed in this Article.⁷³

Similarly, the broadly used term “data exclusivity” or “data protection” is also inadequate for describing the various kinds of RCSs. This term was originally used to describe some of the earlier RCSs, including the famous new chemical entity (NCE) exclusivity created under the Hatch-Waxman Act. As such, it appears that the fame of the Hatch-Waxman regime as well as the absence of a better term to describe RCSs in general have made “data exclusivity” synonymous with any and all kinds of RCSs. However, as explained later in this paper, data exclusivity is but one kind of RCS having its own specific characteristics and purpose.⁷⁴ Therefore, using the term “data exclusivity” as a general name for all RCSs is both overbroad and a mischaracterization because it fails to capture the novel qualities and unique purposes of many particular RCSs.

Being more specific and accurate, the new name “regulatory competitive shelter” is, therefore, not only a better descriptor of the benefits discussed in this Article, but also avoids the conflation of different issues that might result from overbroad and inaccurate use of some of the “old” terms.

E. Innovation-Incentivizing Regulatory Competitive Shelters—Common Motifs

Owing to their structure and mechanism, RCSs meant to promote technological innovation have several noteworthy common features.

1. Limitation in Time

While non-RCS exclusivities may or may not be limited in time, all RCSs have a predetermined statutory term.⁷⁵ Because the ultimate purpose of RCSs

Service, which receives special federal protection from competition. 18 U.S.C. §§ 1693–1699 (2012); 39 U.S.C. §§ 601–606 (2012) (prohibiting private competition within the boundaries of the USPS’ monopoly with the threat of civil and criminal sanctions).

⁷⁰ Administered by the Plant Variety Protection Office in the Department of Agriculture instituted under the Plant Variety Protection Act. *See* Pub. L. No. 91-577, 84 Stat. 1542 (1970) (codified at 7 U.S.C. §§ 2321–2583 (2012)).

⁷¹ Administered under 15 U.S.C. §§ 1051–1072 (2012).

⁷² *See infra* notes 167–68 and accompanying text.

⁷³ *See supra* Part II.A.

⁷⁴ *See supra* Part II.C.

⁷⁵ *See infra* Part III.

is to provide incentives for technological innovation—an ongoing process by definition—and because competition is perceived as the drive for innovation, RCSs ought not to be indefinite. Rather, RCSs seek to confer upon their beneficiaries competitive advantages sufficient to recoup their expenses and compensate them for their time and effort. An indefinite competitive advantage would achieve the opposite result by making such RCSs' beneficiaries complacent and preventing potential competitors from ever competing effectively. The temporariness of RCSs is essential in order to promote the former and prevent the latter.

2. *Low Contestability*

Because they are a result of agency action and involve no conferral of an identifiable right on their beneficiaries, contesting RCSs is difficult and can only be done by challenging the action or non-action of the relevant administrative agency, e.g., by calling into question the agency's "failure" to approve an application to market a regulated product or by granting one inappropriately.⁷⁶ If one is to view RCSs as the consequence of "agency inaction," the prospects of successful challenges in court are low from the outset because under current Supreme Court precedent, challenging administrative agencies' inaction is unlikely to be successful.⁷⁷ Furthermore,

⁷⁶ Compared with patents, for example—another form of administratively created exclusivity meant to provide incentives for the development of technology—RCSs are relatively unsusceptible to legal attacks. This is because patents, while presumed valid upon issuance, are subject to several different types of challenges to their validity that may arise in several different settings, including post-issuance proceedings in the USPTO, defense arguments in patent infringement suits, and suits for a declaratory judgment. Such challenges can and often do result in the partial or complete invalidation of the challenged patents. See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205–07 (1998) (reporting a 46% invalidity rate in patent litigation); Kimberly A. Moore, *Judges, Juries and Patent Cases—An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 390 (2000) (reporting a 33% invalidity rate in patent trials alone). As a result, patents are often viewed as substantially exposed to legal challenges throughout their term. See Brill, *supra* note 26, at 6 ("Patents can, and frequently are, subject to legal challenge and therefore contain some amount of uncertainty for the patent holder. Data exclusivity is not challengeable in court and therefore is not uncertain.").

⁷⁷ See *Heckler v. Chaney*, 470 U.S. 821, 831 (1985) ("This Court has recognized on several occasions over many years that an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion."). The low likelihood of success of an attempt to challenge administrative agencies' inaction is especially true in the context of drug law. See *id.* at 835–36 (rejecting the argument that the FDCA's prohibitions of "misbranding" and the introduction of "new drugs" absent agency approval supply courts with "law to apply" and, accordingly, that they do not provide a basis for judicial review of an FDA decision not to take enforcement action in the area of drug law); *K-V Pharm. Co. v. U.S. Food & Drug Admin.*, 889 F. Supp. 2d 119, 133 (D.D.C. 2012) (refraining from compelling the FDA to

challenging an agency's interpretation of laws instituting RCSs would be subject to the exacting review standard of the *Chevron* doctrine under which courts usually defer to agency decisions⁷⁸ unless a decision is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law."⁷⁹ As recognized by the District Court for the District of Columbia, "[t]his standard of review is narrow and highly deferential; it presumes agency action to be valid, and it prohibits a court from substituting its judgment for that of the agency."⁸⁰ The deference afforded to agency decisions is all the more justified and necessary in matters involving RCSs, which are typically "complex and highly technical [and] in which the identification and classification of relevant criteria require significant expertise and entail the exercise of judgment grounded in policy concerns."⁸¹

Hence, despite the fact that some RCS regimes are subject to agency-specific pathways for challenging agency decisions (including ones involving RCSs),⁸² and although lawsuits against administrative agencies regarding their decisions on matters involving RCSs are not unheard of, RCSs are relatively unsusceptible to legal challenges.⁸³ Indeed, the low success rate of claims

take enforcement action against compounding pharmacies); *see also* Brill, *supra* note 26, at 6 ("Data exclusivity is not challengeable in court . . .").

⁷⁸ *See* *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984) ("We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme . . ."). Under the *Chevron* doctrine, courts generally grant agencies' discretionary decisions and actions, which rely on statutes on whose administration they are in charge, a great measure of deference and are not easily persuaded to set them aside so long as: (1) "Congress has [not] directly spoken to the precise question at issue;" and (2) "the agency's answer is based on a permissible construction of the statute." *Id.* at 842–43. If both of these conditions are met, then the agency's construction of the statute receives "considerable weight" and "the principle of deference to administrative interpretations" ought to be followed. *Id.* at 844.

⁷⁹ 5 U.S.C. § 706(2)(A) (2012).

⁸⁰ *See* *ViroPharma, Inc. v. Hamburg*, 898 F. Supp. 2d 1, 16–17 (D.D.C. 2012).

⁸¹ *See* *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 505 (1994).

⁸² For example, FDA law provides parties seeking to challenge or call into question the agency's decisions involving RCSs with a regulatory petition mechanism known as "citizen petition." *See* 21 C.F.R. § 10.30 (2014).

⁸³ Of more than two dozen court opinions dated through early 2013 analyzed by the author, in which issues directly involved an administrative agency's decision affecting the disposition of an RCS, challenges of the agency decisions succeeded in only 15% of the cases. *See* Yaniv Heled, *RCS Cases Analysis* (2014) (unpublished document) (on file with author). On the other hand, agency decisions were upheld in 77% of the cases (the remaining cases included no conclusive result). *Id.* Notably, the rate of overturning agency decisions is disproportionately high in cases involving the 180-day generic exclusivity RCS instituted under the Hatch-Waxman Act. *See infra* notes 171–72 and accompanying text. This RCS was the topic of dispute in 100% of the cases in which agency decisions affecting the disposition of an RCS were overturned. *Heled, supra*. In other words, the rate of overturning agency decisions affecting the disposition of an RCS *other than* the 180-day generic exclusivity under the Hatch-Waxman Act is 0%. *Id.*

challenging agency decisions pertaining to RCSs as well as the relative rarity of such cases (as compared to patent infringement lawsuits, for example) supports the view that RCSs are a reliable and effective means of conferring competitive advantages.⁸⁴

This hardiness, while highly valued by beneficiaries of RCSs, also has potentially troubling ramifications. Namely, the same characteristics that make RCSs less susceptible to legal challenges also render them less vulnerable to routine judicial review than other administratively granted benefits. Furthermore, because RCSs are a byproduct of agency decisions that often do not directly pertain to the RCSs themselves (e.g., whether to approve a drug for marketing), RCSs are even less likely to be the subject of a legal challenge in and of themselves. While there do not seem to be concrete examples of systemic impropriety of RCS awards or abuse of RCSs, a low frequency of judicial review of RCSs in general certainly raises such concern. Notably, this concern is further exacerbated where the agencies that administer RCS regimes are subject to a risk of capture, which in turn might even increase the risk of RCSs being improperly awarded or abused.⁸⁵

The natural result is that, for both good and bad, RCSs are widely considered a potent benefit for their recipients. This potency lends itself to a highly predictable business environment, thereby encouraging reliance on RCSs by their beneficiaries.⁸⁶ In practical terms, RCS-beneficiaries can expect

At least part of the explanation for the relatively high overturning rate of agency decisions involving the 180-day generic exclusivity RCS instituted under the Hatch-Waxman Act may be attributable to objective difficulty in administering the relevant statutory language, which courts have described as “far from a model of legislative draftsmanship,” “cumbersome,” and “very confusing and ambiguous.” *See* *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1069 (D.C. Cir. 1998) (citations omitted).

⁸⁴The number of reported cases addressing issues that directly pertain to RCSs is dwarfed when compared, for example, with the number of reported patent lawsuits, which measure in the thousands each year. The number of patent cases reported in Westlaw, for instance, for the years 2008, 2009, 2010, 2011 and 2012 is, respectively, 2103, 2126, 2097, 2098, and 2314 for each of those years. Westlaw search conducted Mar. 14, 2015.

⁸⁵Regulatory or agency capture occurs when a regulatory body or agency created to regulate certain industries or sectors in the public’s interest instead advances the commercial or special interests of the industries or sectors it is charged with regulating. Thomas W. Merrill, *Capture Theory and the Courts: 1967–1983*, 72 CHI.-KENT L. REV. 1039, 1060–62 (1997).

⁸⁶*See, e.g.,* BIOTECH. INDUS. ORG. (BIO), A FOLLOW-ON BIOLOGICS REGIME WITHOUT STRONG DATA EXCLUSIVITY WILL STIFLE THE DEVELOPMENT OF NEW MEDICINES 4, available at https://www.bio.org/sites/default/files/FOBMarketExclusivity_050307_0.pdf, archived at <http://perma.cc/S59R-P77J> (“[A] 14-year period of data exclusivity serves essentially as an insurance policy that provides the innovator with some certainty of protection”); Henry Grabowski, Genia Long & Richard Mortimer, *Data Exclusivity Periods for Biologics: Updating Prior Analyses and Responding to Critiques* 4 (Duke Univ. Dep’t of Econ., Working Paper No. 2008-10, 2008), available at http://public.econ.duke.edu/Papers/PDF/Data_Exclusivity_Periods_for_Biologics.pdf, archived at <http://perma.cc/C7FA-FN85> (arguing that the purpose of the market exclusivity

to reap the full benefits that are the result of their respective RCSs unless one of two unlikely events occurs: (1) the RCS benefitting them is found to be based on fraud, or (2) the agency decision that triggered the RCS is declared outright illegal under the exacting standard of the Administrative Procedure Act.⁸⁷

3. *Specificity*

Because they are a byproduct of agency regulation, RCSs are by their nature “tailor-made” for particular areas of regulation, industries, or technology.⁸⁸ This specificity, in turn, makes RCSs highly variable in (1) their length, (2) their triggering events, and (3) their effects, which are dependent on the regulatory powers of the agency that administers each RCS.⁸⁹

4. *Flexibility*

The fact that each and every RCS regime is “tailor-made” also makes RCSs highly flexible both as a regulatory tool and as an instrument of public policy. When establishing RCS regimes, legislators and policymakers are able to craft RCSs in a manner aimed at achieving a wide range of goals by controlling the variables characterizing RCSs.⁹⁰ Primarily, these variables are the length of the RCS, its triggering event, and the nature of the competitive shelter created.⁹¹ Additional variables may include the renewability of the

for biological product developers is to provide them “with an ‘insurance policy’ against the potential failings of patent protection for biologics”); Henry Grabowski & Joseph DiMasi, *Biosimilars, Data Exclusivity, and the Incentives for Innovation: A Critique of Kotlikoff’s White Paper* 4–8 (Duke Univ. Dep’t of Econ., Working Paper No. 2009-02, 2009), available at http://public.econ.duke.edu/Papers/PDF/FinalDraft2_5_09.pdf, archived at <http://perma.cc/9EGX-ZFP9> (“[F]rom the standpoint of innovative firms, [regulatory competitive shelter] protection provides a back-up or insurance policy to the patent system.”).

⁸⁷ See 5 U.S.C. § 706(2)(A) (2012) (directing reviewing courts to hold unlawful and set aside actions that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law”).

⁸⁸ This is, possibly, the reason for the fact that, to date, RCSs have not been discussed as such, but rather, almost always, in the particular context of their specific regulatory framework and technological contexts.

⁸⁹ A possible explanation for the specificity of RCSs is that they are tailored not only to particular regulatory frameworks, industries, or technologies but also are designed so as to facilitate the creation of follow-on versions of the original product, which are expected to be as close as possible to the original product. In other words, RCSs must be specific because they are made to facilitate imitations of highly specific products.

⁹⁰ See Eisenberg 2012, *supra* note 14, at 184.

⁹¹ This flexibility stands in sharp contrast to the rigidity of the patent system and the tremendous difficulties involved in making changes to it. See Thomas, *supra* note 14, at 370–71 (contrasting the ease of changing RCS regimes to the difficulties involved in making changes to the patent system).

RCS (namely, the ability to re-trigger the RCS term), the RCS being subject to particular review and appeal mechanisms (including judicial review), and more.

5. *Clear Boundaries*

Owing to their high level of specificity, the nature and extent of the benefits conferred by RCSs are usually very clear.⁹² Thus, beneficiaries of RCSs usually know with a high level of certainty *what* is covered by the RCS (usually a specific product), for *how long*, and *against whom* or under *what circumstances*. Such clarity stands in sharp contrast to uncertainties that surround other regulatory benefits and exclusivities. The most obvious example of a regulatory exclusivity riddled with such uncertainties is patents, whose scope, length, and even validity are often the topic of disagreement and dispute among courts.⁹³ The clarity of the benefits conferred by RCSs, in turn, promotes legal certainty, which further increases the value of RCSs to business entities.

6. *Low Risk of Imposing Impediments to R&D*

Because RCSs mostly relate to products, rather than to the underlying technologies present in such products (as with patents), RCSs in and of themselves do not preclude research involving the approved product (downstream) or the underlying technology in the product (upstream). Rather, RCSs only impair one's ability to compete with a previously-approved product that is the subject of an RCS.⁹⁴ In this respect, RCSs are unlike patents, which provide a very limited ability to conduct research involving the patented technology in general and outside of the context of FDA filings in particular.⁹⁵

⁹² This is not to say that the onset of any specific RCS is known, as in most cases administrative agencies do not publicize the fact that an RCS has been triggered. A notable exception to this general rule is the FDA's Orange Book, which includes notice of existing RCSs pertaining to pharmaceutical products. See *Orange Book: Approved Drug Products with Therapeutic Equivalence*, FDA, <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm> (last updated May 17, 2013), archived at <http://perma.cc/WEC2-RNTN>.

⁹³ The best example of such disagreement is evident from the high reversal rate of district courts' claim construction decisions by the Federal Circuit. See Kimberly A. Moore, *Markman Eight Years Later: Is Claim Construction More Predictable?*, 9 LEWIS & CLARK L. REV. 231, 233 (2005) (finding a reversal rate of 34.5% for appealed claim terms from 1996 through 2003). See generally BESSEN & MEURER, *supra* note 11.

⁹⁴ See Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials*, 98 IOWA L. REV. 1399, 1406–07 (2013) (recognizing this characteristic in the context of market exclusivities).

⁹⁵ While patent law does include a common law experimental use defense for patent infringement, the Federal Circuit has practically construed this defense out of existence. See *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (citations omitted) (holding that, so long as the act is in furtherance of the alleged infringer's business and is

7. Low Administrative Cost

As noted by Professor Aaron S. Kesselheim, RCSs “are politically attractive because they offer support for . . . innovation without direct allocation of taxpayer funds.”⁹⁶ While legislators and policymakers are reluctant generally to pass legislation that requires further expenditures of public funds, RCSs tend to generate no such objections. This may be because RCSs are perceived as “byproducts” of established regulatory mechanisms whose administration (by “tacking them on” to the independently existing regulatory regime) requires no further resources on top of those already spent to administer the regime.

Regardless of the accuracy of this perception,⁹⁷ the administration of RCS regimes as such seems to require relatively little investment of funds.⁹⁸ First, as byproducts of existing regulatory mechanisms that are already in place and funded, little to no additional costs are required in order to create RCSs.⁹⁹ By contrast, other regulatory exclusivities, such as patents, do typically require investment of funds necessary for evaluation of applications and the creation of a mechanism for awarding any implicated rights.¹⁰⁰ Second, because RCSs are relatively unsusceptible to legal challenges, presumably, administrative

not solely “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry,” the act does not qualify for the experimental use defense). A notable exception to this exists where the research activities are done “solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.” 35 U.S.C. § 271(e)(1) (2012).

⁹⁶ Aaron S. Kesselheim, *Using Market-Exclusivity Incentives to Promote Pharmaceutical Innovation*, 363 NEW ENG. J. MED. 1855, 1855 (2010) [hereinafter Kesselheim 2010].

⁹⁷ This perception is not necessarily fully grounded in economic reality. For example, the Congressional Budget Office estimated that market exclusivity provisions in a recently instituted RCS regime would cause significant direct expenditures over the following decade. See CONGRESSIONAL BUDGET OFFICE, COST ESTIMATE, H.R. 5651: FOOD AND DRUG ADMINISTRATION REFORM ACT OF 2012, at 8 (2012).

⁹⁸ These assumptions do not apply, of course, if an entire regulatory framework is instituted *for the sake* of establishing an RCS regime. While the author is not aware of an example of such a case, should this occur, the cost of administering the RCS should be viewed as the cost of administering the regulatory framework.

⁹⁹ On the other hand, RCSs may also be viewed as a regulatory mechanism to avoid raising taxes in order to fund the development of technology and, instead, rolling over the costs of development of new technology to the public via the high prices charged by RCS-beneficiaries for their products.

¹⁰⁰ To illustrate, the budgetary requirements of the USPTO for its patent-related activities in the fiscal year 2015 were about \$2.9 billion. See U.S. PATENT & TRADEMARK OFFICE, FISCAL YEAR 2015 PRESIDENT’S BUDGET: THE USPTO CONGRESSIONAL BUDGET JUSTIFICATION 15 Fig. 2 (2014), available at <http://www.uspto.gov/about/stratplan/budget/fy15pbr.pdf>, archived at <http://perma.cc/AA96-83NV>.

agencies only need to litigate their decisions involving RCSs infrequently and their expenditure on such litigation is relatively low.¹⁰¹

III. A SURVEY OF FEDERAL REGULATORY COMPETITIVE SHELTER REGIMES

To date, federal law establishes eight different RCS regimes and fifteen specific RCSs listed in Table 3 below.¹⁰² This part reviews these regimes.

¹⁰¹ Most litigation involving RCSs typically does not involve a direct challenge of the RCS but rather of the decision of the administering agency that gave rise to the RCS or some ancillary aspect thereof. *See supra* note 83.

¹⁰² The author is not aware of additional freestanding RCS regimes instituted under federal law.

Table 3: *RCS Regimes Established to Date*

RCS name and instituting statute	Year	Agency	RCS type	Length (years)	Comments
Pesticide exclusivity under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)	1978	EPA	Data	10 + 3x1	Up to three one-year extensions for approval of “minor uses” of the pesticide
Orphan drug exclusivity under the Orphan Drug Act	1983	FDA	Market	7	A non-patentability requirement was removed in 1985
New chemical entity (NCE) exclusivity under the Hatch-Waxman Act	1984	FDA	Market and Data	5	May be shortened to four years by a follow-on applicant challenging the beneficiary’s patents pertaining to the product under exclusivity
New approved use under the Hatch-Waxman Act	1984	FDA	Market	3	
Generic exclusivity under the Hatch-Waxman Act	1984	FDA	Generic	0.5 (180 days)	
New chemical entity exclusivity under the Hatch-Waxman Act for drugs approved between Jan.	1984	FDA	Market	10	No longer applicable

RCS name and instituting statute	Year	Agency	RCS type	Length (years)	Comments
1, 1982, and Sep. 24, 1984					
New chemical compound exclusivity under the Generic Animal Drug and Patent Term Restoration Act (GADPTRA)	1988	FDA	Market and Data	5	May be waived in a non-food animal drug so as to regain it for the same chemical compound in a food animal drug approved at a later time
New approved use under the Generic Animal Drug and Patent Term Restoration Act (GADPTRA)	1988	FDA	Market	3	
Generic exclusivity under the Generic Animal Drug and Patent Term Restoration Act (GADPTRA)	1988	FDA	Generic	0.5 (180 days)	
Pediatric exclusivity under the FDA Modernization Act of 1997	1997	FDA	Market	+ 0.5	Not a "standalone" RCS; may only be "tacked on" other already existing exclusivities under the Hatch-Waxman Act, ODA and BPCIA

RCS name and instituting statute	Year	Agency	RCS type	Length (years)	Comments
Class III medical device exclusivity under the FDA Modernization Act of 1997	1997	FDA	Data	6	
New product exclusivity under the Biologics Price Competition and Innovation Act (BPCIA)	2010	FDA	Market	12	
	2010	FDA	Data	4	
Generic exclusivity under the Biologics Price Competition and Innovation Act (BPCIA)	2010	FDA	Generic	1–3.5	Length to be determined based on certain factors enumerated in the Act
Qualified infectious disease product designation under the Generating Antibiotic Incentives Now (GAIN) Act	2012	FDA	Market and Data	+ 5	Not a “standalone” RCS; may only be “tacked on” other already existing exclusivities under the Hatch-Waxman Act, ODA and BPCIA

A. Regulatory Competitive Shelters in Pesticides

Although the best-known RCS regime is probably the one instituted under the Hatch-Waxman Act,¹⁰³ the first RCS instituted by Congress was created by amendments made to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)¹⁰⁴ in the Federal Pesticide Act of 1978.¹⁰⁵ Under the FIFRA amendments, pesticides must be registered with the Environmental Protection Agency (EPA) prior to their sale in interstate commerce.¹⁰⁶ Receiving approval under FIFRA typically requires submission of data to the EPA to demonstrate the safety of the particular pesticide compound.¹⁰⁷ The 1978 amendments to FIFRA created a ten-year exclusivity period, which could be waived at will, for data submitted by manufacturers of pesticide products where the data pertains to a new active ingredient or a new use of a known ingredient.¹⁰⁸ This ten-year data exclusivity period is then followed by an additional five-year mandatory compensation period, during which the EPA may consider previously submitted data “only if the [secondary] applicant has made an offer to compensate the original data submitter”¹⁰⁹ After expiration of the five-year mandatory licensing/compensation period, the data becomes freely available for use in follow-on applications without any need to receive the permission of the original data submitter or offer compensation for the data.¹¹⁰

In other words, under the RCS regime instituted by the 1978 amendments to FIFRA, a follow-on applicant (M2) for a version of a pesticide product previously approved (P1) by the EPA (AA) seeking to rely on information (D) submitted as part of an application for the approval of the original pesticide product for the approval of its own follow-on product (P2) is unable to do so for a period of ten years (T=10 years) without the prior approval of the original manufacturer and data submitter (M1).¹¹¹ This ten-year data exclusivity period

¹⁰³ See *infra* Part III.C.

¹⁰⁴ Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), ch. 125, 61 Stat. 163 (1947) (codified as amended at 7 U.S.C. §§ 136–136w-8 (2012)).

¹⁰⁵ Federal Pesticide Act of 1978, Pub. L. No. 95-396, 92 Stat. 819 (codified at 7 U.S.C. §§ 136–136w-8).

¹⁰⁶ 7 U.S.C. § 136a(a).

¹⁰⁷ *Id.* In the context of FIFRA, safety is defined as the lack of “unreasonable adverse effects on the environment.” 7 U.S.C. § 136(bb).

¹⁰⁸ 7 U.S.C. § 136a(c)(1)(F)(i); see also ENVTL. PROT. AGENCY OFFICE OF PESTICIDE PROGRAMS, QUESTIONS AND ANSWERS—EXCLUSIVE USE DATA PROTECTION FOR MINOR USE REGISTRATIONS 2 (2014), available at <http://www.epa.gov/pesticides/minoruse/exclusive-use-questions.pdf>, archived at <http://perma.cc/BXM9-UMSM>.

¹⁰⁹ 7 U.S.C. § 136a(c)(1)(F)(iii). This subsection further creates an elaborate scheme for resolution of disputes regarding the amount of the compensation, including a mandatory arbitration between the parties in case of a dispute. *Id.* Notably, disagreement between the parties regarding the compensation will not delay registration by the EPA. *Id.*

¹¹⁰ 7 U.S.C. § 136a(c)(1)(F)(iv).

¹¹¹ See *id.*

is then followed by a five-year mandatory compensation/licensing period, which is not an RCS.¹¹² Rather, the five-year mandatory compensation/licensing period constitutes a *different* mechanism for creating incentives for innovation, which complements the stricter (and more developer-favorable) RCS component of the FIFRA regime.

In 1998, Congress added to the FIFRA RCS regime an option to extend the ten-year data exclusivity period by one year for every three new “minor uses” approved by the EPA for the original pesticide product.¹¹³ Notably, such extension is only available up to three times in each pesticide product (up to a total of thirteen years of data exclusivity) and cannot be granted for “minor uses” registered more than seven years after the onset of the ten-year data exclusivity period.¹¹⁴ Furthermore, FIFRA instructs the EPA to grant such one-year extensions only after consulting with the Secretary of Agriculture and subject to a determination that certain public policy considerations are applicable.¹¹⁵

The history of the FIFRA RCS regime is long and complicated and exceeds the scope of this Article. However, being the first RCS regime on record, there are several interesting facets of the evolution of the FIFRA RCS regime that are worth describing. Originally, the 1947 version of FIFRA did not prohibit the disclosure of information relating to pesticide products.¹¹⁶ During the early 1970s, several key processes and developments took place that would eventually result in the FIFRA RCS. Among these were the ongoing increased use of pesticides in agriculture and concerns about their potential harmful effects on human and animal health¹¹⁷ and the establishment

¹¹² See *supra* note 109.

¹¹³ 7 U.S.C. § 136a(c)(1)(F)(ii). A “minor use” is defined as “the use of a pesticide . . . where: (1) the total United States acreage for the crop is less than 300,000 acres . . . ; or (2) the [EPA], in consultation with the Secretary of Agriculture, determines that” there is insufficient economic incentive to apply for registration of the product for such use independently and one of four other public policy considerations is applicable. 7 U.S.C. § 136(l); see *infra* note 115.

¹¹⁴ 7 U.S.C. § 136a(c)(1)(F)(ii).

¹¹⁵ These considerations are: “(I) there are insufficient efficacious alternative registered pesticides available for the use [in a particular crop]; (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health; (III) the minor use pesticide plays or will play a significant part in managing pest resistance; or (IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.” See 7 U.S.C. § 136a(c)(1)(F)(ii)(I)–(IV).

¹¹⁶ See *Union Carbide Agric. Prods. Co. v. Costle*, 632 F.2d 1014, 1016 (2d Cir. 1980) (“As enacted in 1947, FIFRA did not specifically prohibit the USDA from publicly disclosing submitted data or from using data supplied by one applicant to determine whether to register a pesticide offered subsequently by another.”).

¹¹⁷ See *Federal Pesticide Control Act of 1971: Hearings Before the H. Comm. on Agric.*, 92d Cong. 170 (1971) (statement of W.B. Ennis, Jr., Chief of Crops Protection Research Branch, United States Department of Agriculture) (“Since 1940 we have witnessed agricultural changes This has come about primarily because of . . . (6) control of damaging weeds, diseases, insects, and other pests and parasites.”)

of the EPA and its charge with the administration of FIFRA instead of the Department of Agriculture.¹¹⁸ Another significant development was the amendment of FIFRA in 1972 so as to require a showing that pesticide products seeking registration would not “cause unreasonable adverse effects on the environment.”¹¹⁹ All of these factors resulted in heightened requirements for scientific data regarding pesticide products as a condition for registration by the EPA.¹²⁰ This, in turn, imposed increased financial burdens on developers of pesticide products who were now required to invest substantial resources in complying with the EPA data requirements.¹²¹ As the heightened data requirements posed by the EPA under FIFRA increased financial burdens on developers of pesticide products, developers seem to have become less and less tolerant of certain EPA practices involving the disclosure and use of such data.

Traceable back to the early days of the FIFRA RCS regime, the USDA, which was originally in charge of administering FIFRA, maintained the practice of using data submitted by original pesticide product developers in the review and approval of subsequent applications for registration of follow-on versions of such products.¹²² Concerned about free-riding by subsequent applicants, developers of original pesticide products sought to curb this practice or at least limit it in a manner that would minimize their exposure to financial loss owing to the sharing of data about their products. A heated public policy debate ensued, which epitomized all of the key features of similar debates surrounding later RCS regimes.¹²³

On one side of the debate were proponents of pesticide developers who advocated for stronger protection of data submitted to the EPA in connection

¹¹⁸ See Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15,623 (Oct. 6, 1970); *Union Carbide*, 632 F.2d at 1016 (“The United States Department of Agriculture (USDA) administered the registration program from 1947 until 1970, when EPA assumed that responsibility.”).

¹¹⁹ Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, §§ 3(c)(5)(C)–(D), 86 Stat. 973, 980–81.

¹²⁰ See *Union Carbide*, 632 F.2d at 1016 (“This costly research and lengthy development process produce data that define the peculiar characteristics of the pesticide submitted for registration . . . [and] must be submitted to obtain registration.”).

¹²¹ *Id.*; *Federal Pesticide Control Act of 1971: Hearings Before the H. Comm. on Agric.*, at 331 (statement of Richard H. Wellman, Vice President, Process Chemicals Division of Union Carbide Corporation) (arguing that newer and higher regulatory barriers were being placed in front of industry in their attempts to develop new pesticides and that the cost of developing the necessary data for an application in support of registration was heavy).

¹²² See *Union Carbide*, 632 F.2d at 1016 (“[I]t appears that the USDA made no public disclosures of data but did make use of data on hand in evaluating later applications.”).

¹²³ See, e.g., H.R. REP. NO. 95-663, at 41–42, 58 (1977) (describing a debate regarding the appropriate length, type, and purpose of proposed RCS regimes for FIFRA and the dispute surrounding the definition of proprietary data).

with applications for registration of pesticide products.¹²⁴ The National Agriculture Chemical Association, for example, argued that by referring to data submitted in connection with an earlier application as part of its review of subsequent applications the EPA was undermining incentives for the development of new pesticides.¹²⁵ Proponents of pesticide developers advocated for the institution of long RCSs during which the EPA would not be allowed to use previously submitted data, which—according to them—would prevent free-riding and provide additional incentive for R&D.¹²⁶

On the other side of the debate were those who advocated for little or no exclusivity in the data submitted to the EPA. Among them were proponents of public access to the information submitted to the EPA as well as those concerned over what they saw as a potentially wasteful and unjustified extension of monopolies in pesticide products via the institution of “quasi-patents.”¹²⁷

The length of the FIFRA data exclusivity was a topic of particularly intense debate. While proponents of product developers strongly advocated for ten-year data exclusivity, their opponents objected to the institution of any exclusivity period or would accept, at most, a reasonable compensation requirement. Others preferred reaching a “middle-ground” comprised of five years of data exclusivity followed by an additional period of five years during which a compensation requirement would apply.¹²⁸ However, as pointed out by the EPA during the legislative debate that preceded the enactment of the Federal Pesticide Act:

[We] should be mindful . . . [that] neither approach has had a fair test of implementation It should be noted that EPA economists who analyzed the 7-year compensation period in S. 1678 determined that that period was sufficient to provide a return on the data investment commensurate with other expenditures by pesticide developers. If Congress wishes to confer a “bonus” reward to data developers, extending the compensation period to the point where the rewards equal those of the exclusive use period is an alternative that merits consideration.¹²⁹

¹²⁴ *Federal Pesticide Control Act of 1971: Hearings Before the H. Comm. on Agric.*, at 331.

¹²⁵ *Id.*

¹²⁶ See H.R. REP. NO. 95-663, at 41 (reasoning provided by Rep. Thone for his proposal of a ten-year period of data exclusivity).

¹²⁷ See H.R. REP. NO. 92-511, at 69, 72 (1971) (remarks of Reps. Foley & Dow); S. REP. NO. 92-970 at 12–13 (1972) (letter from the Attorney General); H.R. REP. NO. 95-663, at 41, 53–54 (1977) (reasoning provided by Rep. Fithian for his proposal to provide appropriate compensation in lieu of data exclusivity; letter from the EPA expressing preference for compensation of product developers for use of their data over exclusivity in such data).

¹²⁸ See, e.g., H.R. REP. NO. 95-663, at 41–43, 58.

¹²⁹ *Id.* at 53.

Indeed, the EPA's polite use of deferential language—"[i]f Congress wishes to confer a 'bonus' reward," etc.—barely excuses the fact that none of the positions taken up by the participants in the debate seem to have been founded on any reason-based calculation or empirical data.¹³⁰ Unfortunately, this sad reality also characterized later RCS regimes.

Eventually, in 1978, Congress amended FIFRA by enacting the Federal Pesticide Act of 1978 (FPA), which revised FIFRA's data-consideration and data-disclosure provisions and instituted FIFRA's RCS regime.¹³¹ Attempting to strike a balance between the various interests involved,¹³² a crucial part of these revisions was FPA's authorization of the EPA to disclose health, safety, and environmental data to qualified requesters.¹³³ Such disclosure was meant to take place *regardless* of whether the data may be classifiable as containing trade secrets, but excluding information that would reveal "manufacturing or quality control processes," inert ingredients added to a product, and methods of testing or measuring their quantity *unless* the EPA has first determined that such disclosure "is necessary to protect against an unreasonable risk of injury to health or the environment."¹³⁴ Yet, this balance failed to satisfy developers of original pesticide products who challenged it as an unconstitutional taking of proprietary information without just compensation or due process of law.¹³⁵ The issue was eventually taken up by the Supreme Court, which held that the EPA's consideration or disclosure of data submitted by an applicant to the agency prior to 1972 or after FPA did not constitute an unconstitutional taking.¹³⁶ Specifically, the Supreme Court held that regardless of whether such data included trade secrets,

with respect to any health, safety, and environmental data that [pesticide product developers] submit[] to EPA after the effective date of the 1978 FIFRA amendments . . . [such developers can]not have . . . a reasonable, investment-backed expectation that EPA would keep the data confidential beyond the limits prescribed in the amended statute itself. [Such developers are] on notice of the manner in which EPA was authorized to use and disclose any data turned over to it by an applicant for registration.

. . . If, despite the data-consideration and data-disclosure provisions in the statute, [a product developer chooses] to submit the requisite data in order to receive a registration, it can hardly argue that its reasonable investment-

¹³⁰ *Id.*

¹³¹ Federal Pesticide Act of 1978, Pub. L. No. 95-396, 92 Stat. 819 (codified at 7 U.S.C. §§ 136–136w-8) (2012).

¹³² H.R. REP. NO. 95-663, at 42.

¹³³ FIFRA §§ 10(d)(1)(A)–(C); 7 U.S.C. § 136h(d).

¹³⁴ 7 U.S.C. § 136h(d).

¹³⁵ See *Union Carbide Agric. Prods. Co. v. Costle*, 632 F.2d 1014, 1017 (2d Cir. 1980) (reversing a temporary restraining order against the implementation of the FPA); *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 987 (1984).

¹³⁶ *Ruckelshaus*, 467 U.S. at 987.

backed expectations are disturbed when EPA acts to use or disclose the data in a manner that was authorized by law at the time of the submission.¹³⁷

The Supreme Court further emphasized that,

such restrictions [as those included in the data sharing provisions] are the burdens we all must bear in exchange for ‘the advantage of living and doing business in a civilized community.’ . . . This is particularly true in an area, such as pesticide sale and use, that has long been the source of public concern and the subject of government regulation.

. . . Thus, as long as [product developers are] aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest, *a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking.*¹³⁸

As for data submitted to the EPA prior to the 1972 Amendments, which was allegedly subject to the general provisions of the federal Trade Secrets Act, and not subject to the 1972 FIFRA amendments that explicitly addressed such data,¹³⁹ the Supreme Court held that,

the Trade Secrets Act is not a guarantee of confidentiality to submitters of data, and, absent an express promise, [a product developer] had no reasonable, investment-backed expectation that its information would remain inviolate in the hands of EPA Thus, with respect to data submitted to EPA in connection with an application for registration prior to October 22, 1972, the Trade Secrets Act provided no basis for a reasonable investment-backed expectation that data submitted to EPA would remain confidential.

A fortiori, the Trade Secrets Act cannot be construed as any sort of assurance against internal agency use of submitted data during consideration of the application of a subsequent applicant for registration.¹⁴⁰

Moreover, the Supreme Court ruled that even in cases in which the consideration of data by the EPA constitutes a taking, the use of such data by the EPA is still “public use” (and therefore permissible under the Fifth Amendment) because “[s]o long as the taking has a conceivable public character, ‘the means by which it will be attained is . . . for Congress to determine.’”¹⁴¹ Specifically, the Supreme Court ruled that,

the public purpose behind the data-consideration provisions is clear from the legislative history. Congress believed that the provisions would eliminate costly duplication of research and streamline the registration process, making new end-use products available to consumers more quickly. Allowing applicants for registration, upon payment of compensation, to use data

¹³⁷ *Id.* at 1006–07.

¹³⁸ *Id.* at 1007–08 (emphasis added).

¹³⁹ *See id.* at 1009–14 (discussing data submitted between October 22, 1972, and September 30, 1978).

¹⁴⁰ *Id.* at 1008–09.

¹⁴¹ *Id.* at 1014 (citations omitted).

already accumulated by others, rather than forcing them to go through the time-consuming process of repeating the research, would eliminate a significant barrier to entry into the pesticide market, thereby allowing greater competition among producers of end-use products.¹⁴²

As mentioned earlier, many of the issues raised during the deliberations and debates that surrounded the institution of the FIFRA RCS regime are the same as those that accompany—some would say plague—RCS regimes and the debates surrounding them to this day. Indeed, many of the issues raised in the context of FIFRA seem to be a staple of regulatory exclusivity regimes in general, including RCSs.

According to the EPA's Pesticide Product Information System (PPIS), the EPA has registered over 95,000 pesticide products under FIFRA.¹⁴³

B. Regulatory Competitive Shelters Under the Orphan Drug Act

The first of several RCS regimes in the area of pharmaceutical technologies, enacted in 1983, the Orphan Drug Act (ODA)¹⁴⁴ institutes a regime of market exclusivities for developers of drugs for rare diseases.¹⁴⁵ Under the ODA, once a pharmaceutical is approved for marketing and “designated under [21 U.S.C. § 360bb] for a rare disease or condition, the [FDA] may not approve another application . . . for such drug for such disease or condition for a [generic applicant] until the expiration of seven years from the date of the approval of the [drug or biologic].”¹⁴⁶ The seven-year exclusivity period under the ODA may be further extended by six months for submission of clinical data involving studies of an orphan drug in the pediatric population.¹⁴⁷

Importantly, the ODA also gives the FDA the authority to effectively rescind the exclusivity in a pharmaceutical product that received orphan drug status by approving another application for the marketing of the same drug for the same rare disease.¹⁴⁸ This authority, however, is only applicable in two

¹⁴² *Ruckelshaus*, 467 U.S. at 1014–15.

¹⁴³ *Pesticide Product Information System (PPIS), Basic Registration Information*, EPA, <http://www.epa.gov/opp00001/PPISdata/> (last visited Dec. 2, 2014), *archived at* <http://perma.cc/K6B7-CH49>.

¹⁴⁴ *See supra* note 4.

¹⁴⁵ *See* 21 U.S.C. § 360bb(a)(2) (2012) (defining “rare disease or condition”). Some well-known examples of rare diseases are Huntington’s disease, amyotrophic lateral sclerosis (ALS) (Lou Gehrig’s disease), and Tourette syndrome. *See Congressional Findings for the Orphan Drug Act*, FDA, <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdca/significantamendmentstothefdca/orphandrugact/default.htm> (last updated July 18, 2013), *archived at* <http://perma.cc/4XWY-P4MJ>.

¹⁴⁶ 21 U.S.C. § 360cc(a)(2) (2012). To clarify, third parties would still be able to have the same pharmaceutical approved during the seven-year exclusivity period for a condition other than the rare disease.

¹⁴⁷ 21 U.S.C. § 355a (2012).

¹⁴⁸ 21 U.S.C. § 360cc(b).

situations: (1) when the original beneficiary of the seven-year exclusivity “cannot assure the availability of sufficient quantities of the drug to meet the needs of persons with the [rare disease]” and (2) where the beneficiary provides written consent to the approval of the subsequent application prior to the expiration of the seven-year exclusivity. Thus, the ODA provides a unique example of giving the administrative agency administering an RCS regime the power to cancel or rescind the exclusivity where the exclusivity jeopardizes the regime’s underlying public policy goals (in the first case) or where it is efficient to do so (in the second case).¹⁴⁹

As is evident from the definition of “rare disease or condition” under the ODA, the rationale behind the legislation of the Act was to create additional financial incentives for the development of drugs for rare diseases where patent law provided insufficient incentives to make the development of such pharmaceuticals financially feasible.¹⁵⁰ At its inception, the ODA required that, in order to qualify for the seven-year market exclusivity, the underlying technology in the pharmaceutical product must be unpatented and unpatentable.¹⁵¹ The reason for this prerequisite was the original perception that where patents are available, they afford sufficient competitive advantages to make the R&D investment in the orphan pharmaceutical worthwhile. Yet, this non-patentability prerequisite was quickly discarded so as to make all pharmaceutical products—regardless of their status under the Patent Act—potential candidates for the seven-year exclusivity.¹⁵² This change was meant “to protect [a] company that developed an orphan drug whose patent had expired or would expire by the time the drug could be tested and approved for use in a rare disease.”¹⁵³ Therefore, “[u]nder the 1985 amendment, the seven year period of market exclusivity would continue to run concurrently with any remaining patent, so the exclusivity only benefits those drugs with little or no patent protection.”¹⁵⁴

¹⁴⁹ FDA regulations implementing the ODA include another exception to the market exclusivity provision in cases where the follow-on drug is “clinically superior” to the drug under exclusivity. See 21 C.F.R. § 316.3(b)(14)(i) (2014).

¹⁵⁰ See *Congressional Findings for the Orphan Drug Act*, *supra* note 145. Under the 1983 Act, an orphan drug was defined as one for which there was “no reasonable expectation that the cost of developing . . . will be recovered from sales . . . of such drug.” Pub. L. No. 97-414, § 526(a)(2), 96 Stat. 2049 (1983) (codified as amended at 21 U.S.C. § 360bb(a)(2) (2012)). The definition was later changed so as to also include “any disease or condition which . . . affects less than 200,000 persons in the United States.” 21 U.S.C. § 360bb(a)(2). Orphan drug products may be entirely unpatentable and could still merit exclusivity under the ODA. 21 U.S.C. § 360bb(a).

¹⁵¹ ODA § 527.

¹⁵² See Orphan Drug Amendments of 1985, Pub. L. No. 99-91, § 2, 99 Stat. 387.

¹⁵³ H.R. REP. NO. 100-473, at 5 (1987); H.R. REP. NO. 99-153, at 3–5 (1985) (describing situations where the non-patentability requirement interferes with the ODA’s purpose).

¹⁵⁴ H.R. REP. NO. 100-473, at 5.

The seven-year RCS that is the crux of the ODA is considered to have been successful in achieving its desired effect—since its passage in 1983, more than 350 drugs and biologics¹⁵⁵ for rare diseases and conditions have been brought into the market as compared with fewer than ten in the decade preceding the passage of the Act.¹⁵⁶ Yet, despite its apparent success, the ODA and its RCS regime have often been criticized for fostering abusive commercial and competitive practices, including charging egregious prices for some orphan drugs.¹⁵⁷ Many amendments have been proposed to the ODA over the years to address some of these concerns, but most of them have been rejected for fear of interfering with the Act's perceived success.¹⁵⁸ Most notably, in 1990 President George H.W. Bush vetoed an amendment to the ODA¹⁵⁹ that would have made it possible for the FDA to rescind the market exclusivity under the statute if the patient population for the drug went above 200,000 people,¹⁶⁰ as well as to grant the seven-year exclusivity jointly to more than one party.¹⁶¹

¹⁵⁵“Biologics” and “drugs” are both classes of pharmaceuticals. For simplicity, “biologics” and “biological products” are pharmaceutical products whose manufacturing involves the use of living organisms and are relatively large and complex molecules whereas “small molecule drugs” (or “drugs” for short), are chemically synthesized and are relatively small and simple. For further discussion of the differences between biologics and drugs, see Heled, *supra* note 13, at 421 n.2.

¹⁵⁶See Kesselheim 2010, *supra* note 96, at 1857 (“Many have hailed the act’s success.”); Frank R. Lichtenberg & Joel Waldfogel, *Does Misery Love Company? Evidence from Pharmaceutical Markets Before and After the Orphan Drug Act*, 15 MICH. TELECOMM. & TECH. L. REV. 335, 348 (2009) (arguing that the Orphan Drug Act “works”); Li-Hsien Rin-Laures & Diane Janofsky, *Recent Developments Concerning the Orphan Drug Act*, 4 HARV. J.L. & TECH. 269, 270 (1991) (“There is little dispute that the Orphan Drug Act has been successful.”); FDA, DEVELOPING PRODUCTS FOR RARE DISEASES & CONDITIONS, <http://www.fda.gov/forindustry/developingproductsforrareconditions/default.htm>, archived at <http://perma.cc/2NSV-MZYE>.

¹⁵⁷See, e.g., S. REP. NO. 102-358, at 2–8 (1992) (discussing some allegedly abusive commercial practices); 134 CONG. REC. S3685, 3686 (1988) (statement of Sen. Kassebaum); 134 CONG. REC. H1018, 1019 (1988) (statement of Rep. Waxman); see also Aaron S. Kesselheim et al., *Characteristics of Clinical Trials to Support Approval of Orphan vs Nonorphan Drugs for Cancer*, 305 JAMA 2320, 2325–26 (2011) (finding that pivotal trials for orphan drugs for cancer approved between 2004 and 2010 were more likely to be smaller and to use nonrandomized, unblinded trial designs and surrogate end points to assess efficacy than trials for non-orphan drugs).

¹⁵⁸See Gary Pulsinelli, *The Orphan Drug Act: What’s Right with It*, 15 SANTA CLARA COMPUTER & HIGH TECH. L.J. 299, 332, 334–35 (1999) (discussing the rejection of certain proposed amendments to the Orphan Drug Act); S. REP. NO. 103-366, at 14–16 (1994).

¹⁵⁹See 137 CONG. REC. H116, 116–17 (1991); H.R. REP. NO. 101-635 (1990).

¹⁶⁰H.R. REP. NO. 101-635, at 4. This proposal was meant to prevent abuses resulting from an orphan drug becoming a “blockbuster.”

¹⁶¹137 CONG. REC. H116, 116–17. The “shared exclusivity” proposal was meant to alleviate some of the ramifications of situations where two or more developers race to obtain FDA approval for the same product, with the inevitable result being that one of them loses the race and its substantial investment in R&D. *Id.*; H.R. REP. NO. 101-635, at 4–5.

Interestingly, the legislative history of the ODA does not include any discussion of the length of the RCS instituted under the Act.¹⁶² Hence, as with the length of the FIFRA RCS, it appears that the determination of seven years as the period of RCSs granted under the ODA was not based on any traceable or verifiable criteria or at least none that is available on the public record.

C. Regulatory Competitive Shelters Under the Hatch-Waxman Act

Well known, widely used, and broadly considered a success story,¹⁶³ the RCS regime under the Hatch-Waxman Act is, for better and for worse, the most prominent example of an RCS regime.¹⁶⁴ The Hatch-Waxman Act creates a regulatory pathway for the approval of generic versions of small-molecule drugs and establishes three exclusivity periods.¹⁶⁵ First, the Hatch-Waxman Act offers original drug manufacturers a five-year RCS period for receiving marketing approval of drugs containing therapeutic chemical compounds—new chemical entities (NCEs)—that have not been previously approved for medical use.¹⁶⁶ During that period the FDA will not accept applications for generic versions of the drug product containing the new chemical compound.¹⁶⁷ Akin to the RCS established under the Orphan Drug

¹⁶² The legislative history of the Orphan Drug Amendments of 1985 includes a cursory reference to this issue. *See* H.R. REP. NO. 99-153, at 6 (1985) (“The Committee selected the period of seven years in current law because that period was thought to be a sufficient time to enable a drug company to recoup a significant amount, if not all, of the cost of development for many orphan drugs.”).

The seven-year period may bear some tangential relation to a perception recited frequently around the early 1980s regarding the loss of seven to ten years of patent protection owing to the lengthy approval proceedings at the FDA. *See generally The Patent Term Restoration Act of 1981: Hearing on S. 255 Before the S. Comm. on the Judiciary*, 97th Cong. (1981) (discussing the perceived loss of patent protection due to the extension of regulatory approval processes of pharmaceuticals). This reasoning, however, has not been directly proposed with relation to the ODA’s seven-year RCS.

¹⁶³ *See supra* note 11; *see infra* note 173 and accompanying text.

¹⁶⁴ *See supra* note 5. For an overview of the Hatch-Waxman Act and its legislative history, *see generally* Mossinghoff, *supra* note 62; THE LEGISLATIVE HISTORY OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 (Allan M. Fox & Alan R. Bennett eds., 1987) [hereinafter FOX & BENNETT].

¹⁶⁵ *See* 21 U.S.C. §§ 355(j)(5)(F)(ii)–(iv), 355a(a)–(c) (2012).

¹⁶⁶ *See* 21 U.S.C. § 355(c)(3)(E)(ii).

¹⁶⁷ *See id.* This exclusivity period is commonly known as “new chemical entity” (NCE) exclusivity. *Id.* However, a generic applicant may file an application for the approval of a generic version of the drug after four years by challenging the patents related to the original product under 21 U.S.C. § 355(j)(5)(B)(iv)(II), thereby effectively shortening the market exclusivity period under the NCE exclusivity to four years while, at the same time, “transforming” it into a data exclusivity. Such a challenge would normally prompt the filing of a lawsuit by the patent owner, which would trigger—regardless of the timing of the challenge with relation to the NCE exclusivity—an additional period of thirty months (or 7.5 years from the date of approval, if the filing was made between NCE years four and five) during which the FDA may not approve the generic application. *See* 21

Act, the purpose of the NCE exclusivity is to offer drug developers additional financial incentives to develop drugs where patent law provides insufficient incentives to make the development of such drugs financially feasible.¹⁶⁸

Additionally, the Hatch-Waxman Act creates a three-year RCS period for conducting supplemental clinical investigations that lead to the approval of an existing drug for treatment of a new medical condition or disease; during that period the FDA will not approve applications for generic versions of the drug product for that new medical use.¹⁶⁹ Like the NCE exclusivity, the three-year exclusivity period is meant not only to provide further incentives for investment in R&D where little or no patent protection is available in a certain drug, but also to provide incentives for further R&D of previously-approved drugs that may have additional medical uses.¹⁷⁰

Finally, the Hatch-Waxman Act seeks to provide incentives for the creation of generic versions of drugs by granting a 180-day exclusivity period to pharmaceutical companies that are the first to file applications for the marketing of generic versions of an original drug product.¹⁷¹ In order to receive the 180-day exclusivity, however, a generic applicant must challenge patents related to the original drug as invalid, unenforceable, or not infringed.¹⁷² The flourishing generic drug market and the generic drug industry are commonly viewed as attributable to this RCS scheme created under the Hatch-Waxman Act.¹⁷³

U.S.C. § 355(j)(5)(B)(iii). Notably, the specific circumstances of the NCE exclusivity are such that in practice it typically lends itself to a 5.5 to 7.5-year market exclusivity period in the protected compound. Eisenberg 2012, *supra* note 14, at 185.

¹⁶⁸ For the idea behind the NCE exclusivity established under the Hatch-Waxman Act, see FOX & BENNETT, *supra* note 164, at 60 (“The original Waxman Committee version . . . would have allowed granting four years of [product] exclusivity only to new chemical entities that for technical or scientific reasons are unpatentable.”); 130 CONG. REC. 24,425 (1984) (statement of Rep. Henry Waxman) (“[T]he amendment provides a 5-year period of exclusive market life for drugs approved for the first time after enactment of the legislation. This provision will give the drug industry the incentives needed to develop new chemical entities whose therapeutic usefulness is discovered late when little or no patent life remains.”).

¹⁶⁹ See 21 U.S.C. §§ 355(c)(3)(E)(iii)–(iv) (2012).

¹⁷⁰ See 130 CONG. REC. 24,425 (1984) (statement of Rep. Henry Waxman) (“This provision will encourage drugmakers to obtain FDA approval for significant therapeutic uses of previously approved drugs.”).

¹⁷¹ See 21 U.S.C. § 355(j)(5)(B)(iv). The benefit embodied in the 180-day exclusivity period for generic manufacturers lies in the recipient’s ability to charge near monopoly prices for its generic version of the drug for the duration of the 180-day exclusivity period. See Gitter, *supra* note 13, at 573 (noting that during the 180-day period the generic drug “shares duopoly prices with the Brand-name drug”).

¹⁷² See 21 U.S.C. § 355(j)(5)(B)(iv)(II). Thus, the Hatch-Waxman Act itself provides incentives to challenge patents related to the original drug product. In this respect, the Hatch-Waxman Act seeks to abolish one monopoly by offering another, shorter one.

¹⁷³ The Hatch-Waxman Act is considered a great success in terms of providing incentives for R&D activities in monetary terms due to the savings attributable to the

Originally, the Hatch-Waxman Act included an additional ten-year RCS for drugs containing new chemical entities that were approved between January 1, 1982, and September 24, 1984.¹⁷⁴ As is evident from these dates, this RCS is no longer applicable.

Despite its success, the RCS regime instituted under the Hatch-Waxman Act has been the subject of much critique. While reviewing the ongoing debate regarding the Hatch-Waxman RCS regime exceeds the scope of this Article, it is worth mentioning some of the most prominent criticisms that have accompanied the Hatch-Waxman RCS regime since its inception. For one, the Hatch-Waxman RCSs have been accused of perverting the patent system by affording exclusive rights in technologies that would have otherwise not merited such rights under patent laws and by creating very powerful rights—“super patents” of sorts—in such technologies that are unchallengeable.¹⁷⁵ Further, some of the Hatch-Waxman RCSs have also been accused of being “gifts” for the pharmaceutical industry at the expense of the public, which allows pharmaceutical companies to charge egregious prices for drugs, sometimes of little innovative value, for prolonged periods of time.¹⁷⁶ In addition, the Hatch-Waxman RCS regime and its complex relation with patent laws have often been cited as creating an opening for various types of abuse, including through such infamous practices as “evergreening”¹⁷⁷ and reverse-

approval of generic versions of innovative drugs. *See* Gitter, *supra* note 13, at 586–87 (reviewing the reasons for what the author describes as the overall success of the Hatch-Waxman Act); Liang, *supra* note 41, at 365 (arguing that the Hatch-Waxman Act has been very successful in bringing cheaper generic versions of drugs to the market while maintaining incentives for continued innovation).

¹⁷⁴ *See* 21 U.S.C. § 355(c)(3)(E)(i). This RCS was meant to serve as a transition regime, a “buffer” of sorts, between the virtually unlimited exclusivity in drugs that existed prior to the enactment of the Hatch-Waxman Act, and the onset of the pathway for the approval of follow-on drug products under the Act. *See* H.R. REP. NO. 98-857, pt. 2, at 16 (1984) (referring to the provision as an “interim rule” for the “transitional period” between January 1, 1982 and the date of enactment of the Hatch-Waxman bill).

¹⁷⁵ *See, e.g.*, 130 CONG. REC. 24,426 (1984) (statement of Rep. Kastenmeier). *But see* Morris *supra* note 11, at 269–70, 273 (arguing that the 180-day generic exclusivity is a perversion of the incentives for brand name companies to develop new drug products because by creating incentives to challenge patents covering such products it effectively reduces expected pharmaceutical patent life).

¹⁷⁶ 130 CONG. REC. 24,425 (1984) (statement of Rep. Henry Waxman). *See also* Jeremiah Helm, Comment, *The Patent End Game: Evaluating Generic Entry into a Blockbuster Pharmaceutical Market in the Absence of FDA Incentives*, 14 MICH. TELECOMM. & TECH. L. REV. 175, 195–96 (2007) (questioning the need for the 180-day generic exclusivity and suggesting that it does not serve its original purpose but rather propagates harmful pricing practices).

¹⁷⁷ Evergreening—also euphemistically known as “life-cycle management”—is a term typically referring to a variety of practices of brand-name pharmaceutical manufacturers aimed at extending exclusivity periods for their products to maintain their revenue streams. *See* Aaron S. Kesselheim, *Rising Health Care Costs and Life-Cycle Management in the*

payment (a.k.a. “pay-for-delay”) arrangements.¹⁷⁸ Finally, critics of the legislative process that resulted in the Hatch-Waxman Act have characterized it as “not the result of thoughtful consideration by committees or by Members of Congress; rather it is the byproduct of a backroom deal between two branches of the drug industry” resulting in “some significant, anticonsumer provisions.”¹⁷⁹

Another interesting aspect of the Hatch-Waxman RCSs is that, like the FIFRA and ODA RCSs, their length has no known verifiable rational basis.¹⁸⁰ Other equally consequential timeframes instituted under the Hatch-Waxman Act and relating to the patent term restoration component of the Act were “strictly arbitrary legislative numbers pulled out of the air.”¹⁸¹ It is not implausible that, like the patent term restoration timeframes, the lengths of the RCS timeframes under the Hatch-Waxman Act were also arbitrary or determined based on what the drafters believed would garner most political agreement rather than on any rational criteria.

D. Regulatory Competitive Shelters in New Animal Drugs

Enacted in 1988, the Generic Animal Drug and Patent Term Restoration Act (GADPTRA)¹⁸² created a RCS regime, which was modeled after the

Pharmaceutical Market, 10 PLOS MED. e1001461 (2013) (defining evergreening and listing examples of specific evergreening practices). Evergreening practices usually involve

mak[ing] relatively minor changes to . . . existing products in order to restart their monopoly-protection clocks. These changes include changing the medication strength of pills[.] . . . changing the form of medication (e.g., switching from pill to capsule), modifying the method of delivery (e.g., from injection to inhalation), expanding indications (applying the medicine to additional conditions), pegylation (which has the effect of reducing doses per time period via time-release mechanisms), and glycosolation [sic] (adding sugar molecules to the medication).

Kotlikoff, *supra* note 58, at 9; *see also* Eisenberg 2007, *supra* note 15, at 354.

¹⁷⁸ *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013) (addressing the legality of reverse payment arrangements); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlements as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1559–60 (2006); Hemphill & Lemley, *supra* note 15, at 949 (proposing changes to the 180-day generic exclusivity RCS regime); Kesselheim, *supra* note 11, at 490 (“In the case of Hatch-Waxman, the 180-day exclusivity period has generated settlement agreements that benefit brand-name and generic drug manufacturers at the expense of patients and payers, by delaying the entry of generic drugs.”); Rumore, *supra* note 11, at 6 (describing pay-for-delay arrangements and patent “evergreening” associated with the Hatch-Waxman Act).

¹⁷⁹ 130 CONG. REC. 24,426 (1984).

¹⁸⁰ The legislative history of the Hatch-Waxman Act includes no discussion of the lengths of the RCSs instituted under the Act or any reference to how these lengths were determined.

¹⁸¹ *See* Mossinghoff, *supra* note 62, at 190.

¹⁸² Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988) (codified in scattered sections of 21 U.S.C.).

Hatch-Waxman Act.¹⁸³ GADPTRA creates a regulatory pathway for the approval of generic versions of drugs—albeit drugs meant for animals¹⁸⁴—that includes: (1) a five-year exclusivity period for animal drugs containing therapeutic chemical compounds that have not been previously approved for medical use, during which the FDA will not accept applications for generic versions of an animal drug product containing the new chemical compound;¹⁸⁵ (2) a three-year RCS period for conducting supplemental clinical investigations that lead to the approval of a new medical use of a previously-approved drug;¹⁸⁶ and (3) a 180-day exclusivity period for companies that are first to file applications for the marketing of generic versions of an original animal drug product.¹⁸⁷ Further, recognizing the difference in commercial value of animal drugs approved for use in non-food animals as opposed to food animals, under GADPTRA, the beneficiary of an NCE exclusivity may waive the five-year NCE exclusivity as it pertains to a non-food animal drug so as to regain it for the same chemical compound once it receives approval for use in food-animals; in such a case, the non-food animal drug would receive the three-year exclusivity discussed below.¹⁸⁸

The purpose of GADPTRA was:

to extend to veterinary drugs . . . the generic competition and restored patent life afforded human pharmaceuticals by the [Hatch-Waxman] Act [and to follow] the same balance struck by Congress in 1984 in both fostering lower prices for generic products while restoring to innovators some of the patent

¹⁸³ See *Animal Drug Amendments and Patent Term Restoration Act of 1986: Hearing on S. 2407 Before the S. Comm. on Labor and Human Res.*, 99th Cong. 2 (1986) [hereinafter *S. Comm. on Labor and Human Res. 1986 Hearing*].

¹⁸⁴ See 21 U.S.C. § 360b(b)(2) (2012).

¹⁸⁵ *Id.* § 360b(c)(2)(F)(i). As is the case under the Hatch-Waxman Act, a generic applicant may file an application for the approval of a generic version of the animal drug after four years by challenging the patents related to the original product, thereby effectively shortening the data-exclusivity period under the five-year exclusivity to four years. *Id.*

¹⁸⁶ See *id.* § 360b(c)(2)(F)(ii)–(iii).

¹⁸⁷ See *id.* § 360b(c)(2)(D)(iv). As with the generic product exclusivities under the Hatch-Waxman Act, in order to receive the 180-day exclusivity a generic applicant must challenge patents related to the original animal drug. See *id.*

¹⁸⁸ 21 U.S.C. §§ 360b(c)(2)(F)(iv)–(v); *Drug Issues: Hearings Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 100th Cong. 144 (1988) (“This provision recognizes that the scientific investigations necessary to gain approval for use in food-producing animals are ordinarily of greater length and of significantly greater cost than those for non-food producing animals.”). This provision was added to the proposed GADPTRA RCS regime at the explicit request of the pharmaceutical industry. See *id.* at 196, 209 (statement of the Animal Health Institute) (representing that “AHI is the national trade association [of the] major manufacturers of animal health products . . . veterinary drugs, and biologics[—]in the United States” and advocating for the inclusion of the RCS waiver option as it pertains to non-food animals).

protection lost primarily during Food and Drug Administration . . . review of premarket approval applications.¹⁸⁹

GADPTRA was met with the same critique as the Hatch-Waxman Act at its early stages.¹⁹⁰ Interestingly, unlike the Hatch-Waxman Act, GADPTRA allows the FDA not only to use data submitted in connection with the review of earlier drug applications, but also to *directly disclose* such information to interested third parties, provided that such third parties commit not to disclose the data to unauthorized persons or use it for the purpose of marketing their products outside of the United States.¹⁹¹

Unlike with all of the aforementioned pieces of legislation, the legislative history of GADPTRA *does* include a discussion, albeit brief, of the appropriate lengths of RCSs instituted under the Act.¹⁹² During a discussion of the version of the bill that was pending before the House of Representatives, two members of the House—Carlos Moorehead, member of the Subcommittee on Courts, Civil Liberties, and the Administration of Justice of the House Committee on the Judiciary, and Thomas Tauke, a member of the House Committee on Energy and Commerce and one of the sponsors of the GADPTRA bill—had the following revealing exchange regarding the lengths of RCSs under the bill during Mr. Tauke's testimony:

Mr. MOORHEAD: . . . It takes a longer period of time for [animal drug products] to recover the costs of their research [than human drug products].

. . . You just do not give [animal drug developers] long enough to recover the costs of the research that they have put into this . . .

. . . [T]hat is my big concern about this thing. We just have not left a big enough [exclusivity] window for it.

Mr. TAUKE: . . . So, now, what we are trying to figure out is what is an appropriate length of time. If you have additional ideas on what the length of time should be, perhaps you can attempt to offer those in the Subcommittee.

I cannot sit here and say . . . I have all the wisdom to tell . . . precisely what the length of time should be. We think we have struck a reasonably good balance [in the GADPTRA bill].

. . . .
Mr. MOORHEAD: . . . [I]t just seems to me we may be throwing a wet blanket on research if we do not allow a much larger [exclusivity] window than we have under this bill.

Mr. TAUKE: . . . In my judgment, . . . the bill . . . strikes an appropriate balance . . .

But a year one way or another or something, probably that is not going to make that much difference.

¹⁸⁹ See S. REP. NO. 99-448, at 2 (1986).

¹⁹⁰ See S. Comm. on Labor and Human Res. 1986 Hearing, *supra* note 183, at 35 (statement of Dr. James Gillin, Chairman-Elect, Animal Health Institute).

¹⁹¹ See 21 U.S.C. § 360b(p).

¹⁹² *Generic Animal Drug and Patent Term Restoration Act: Hearing on H.R. 4982 Before the Subcomm. on Courts, Civil Liberties, and the Admin. of Justice of the H. Comm. on the Judiciary*, 100th Cong. 88–89 (1988).

Obviously, in the human area [of drug research] we have struck the proper balance [with the Hatch-Waxman RCS regime] because research is at record levels.¹⁹³

Apparently, Congress recognized the significant differences between the human drug market and the animal drug market.¹⁹⁴ Yet, the drafters of GADPTRA seem to have been unable to translate the differences between human and animal drugs into modifications of the lengths of the Hatch-Waxman Act's RCSs so as to adapt them to GADPTRA.¹⁹⁵

E. Regulatory Competitive Shelters for Additional Testing in Pediatric Populations Under the Food and Drug Administration Modernization Act

In 1997, Congress passed the Food and Drug Administration Modernization Act of 1997 (FDAMA), which instituted two separate RCS regimes.¹⁹⁶ Under Section 111 of FDAMA, original drug manufacturers may extend an already existing RCS (e.g., under the Hatch-Waxman Act or Orphan Drug Act) by “tacking on” to these periods an additional term of six months of exclusivity¹⁹⁷ for conducting clinical studies of the drug in pediatric populations.¹⁹⁸ Further, if any patent listed in the FDA's Orange Book covers

¹⁹³ *Id.* at 83–85.

¹⁹⁴ Congress clearly recognized that there were profound differences in the regulatory and marketplace circumstances of human drugs and animal drugs. *See, e.g.*, 134 CONG. REC. 29,036–37 (1988) (statement of Rep. Tauke); *The Generic Animal Drug and Patent Term Restoration Act: Hearing on H.R. 5069 Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 99th Cong. 69–70 (1986) (statement of the Animal Health Institute) (highlighting the differences between the testing requirements applicable to human drugs and animal drugs and stating that the provisions in “H.R. 5069 must be changed to reflect the realities of the animal drug marketing, rather than reflecting the human drug industry experience”).

¹⁹⁵ This is evidenced by the wholesale incorporation of the Hatch-Waxman Act's RCS terms into the GADPTRA regime. *Cf. supra* Part III.C.

¹⁹⁶ Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, 111 Stat. 2296 (codified in scattered sections of 21 U.S.C.). For a discussion of the second regime instituted under FDAMA, see *infra* Part III.F.

¹⁹⁷ The extension under FDAMA cannot stand alone when there is no prior exclusivity (RCS or patent) to “tack” it onto. This fact proved problematic later on, when it became evident that FDAMA did not create incentives for studies in pediatric populations where the six-month exclusivity would not apply. *See* S. REP. NO. 107-79, at 7–8 (2001) (discussing the need for the creation of a federal research fund for such studies).

¹⁹⁸ 21 U.S.C. § 355a (2012). To clarify, the exclusivity applies to the product in general and not just for its use in a pediatric population; in fact, the exclusivity may apply even if the product is eventually not approved for use in the pediatric population. The exclusivity, however, may not be “tacked on” if the existing RCS period (on which it is meant to be “tacked”) is set to expire in less than nine months. *Id.* §§ 355a(b)(2), (c)(2).

the drug,¹⁹⁹ then the FDA may not approve any applications for follow-on versions of the drug during a period of six months subsequent to the expiration of such patents.²⁰⁰

Commonly known as “pediatric exclusivity,” the purpose of this RCS is to encourage the collection of safety and efficacy information for drugs when used in the pediatric population so as to allow the “configuration” of existing pharmaceuticals for use in this population.²⁰¹ The institution of the pediatric exclusivity RCS was a response to a neglect of pediatric populations in the ordinary course of clinical testing of new pharmaceutical products due to lack of financial incentives.²⁰² Five years after its institution, in light of its apparent success in obtaining its desired effect,²⁰³ Congress reauthorized the pediatric exclusivity.²⁰⁴ Notably, the reauthorizing act also included the requirement that the FDA publish a summary of studies performed in the pediatric population, which were submitted to the FDA within six months of a change made to the pediatric labeling of the relevant drug.²⁰⁵ Later amendments instituted a mandatory requirement for studies of new drugs in pediatric populations—including the grant of authority to the FDA to require such studies retroactively²⁰⁶—and reauthorized the pediatric exclusivity.²⁰⁷

For the pediatric exclusivity RCS to be triggered, the RCS beneficiary must satisfactorily complete the additional clinical trials required by the FDA and submit the data within the timeframe designated by the FDA. *See Id.* §§ 355a(b)(1), (c)(1), (d)(3), (e)(1).

¹⁹⁹ *See Orange Book*, *supra* note 92.

²⁰⁰ 21 U.S.C. § 355a(b)(1)(B).

²⁰¹ The institution of the pediatric exclusivity RCS was a response to a perceived lack of “systematic means for testing the safety and efficacy of drugs on [sic] the pediatric population.” S. REP. NO. 105-43, at 3 (1997).

²⁰² *Id.* at 51 (citing the fact that less than twenty percent of the prescription medications on the United States market are approved for use in the pediatric population and labeled for pediatric use as a rationale for the need for the pediatric exclusivity RCS).

²⁰³ S. REP. NO. 107-79, at 4–5 (2001) (citing indications to the success of pediatric exclusivity in encouraging drug developers to conduct studies in pediatric populations). The pediatric exclusivity’s success seems to have been reaffirmed in a 2011 report of the United States Government Accountability Office (GAO) report. *See* U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-11-457, REPORT TO CONGRESSIONAL COMMITTEES: PEDIATRIC RESEARCH, PRODUCTS STUDIED UNDER TWO RELATED LAWS, BUT IMPROVED TRACKING NEEDED BY FDA (2011).

²⁰⁴ Best Pharmaceuticals for Children Act, Pub. L. No. 107-109, 115 Stat. 1408 (2002).

²⁰⁵ *Id.*

²⁰⁶ Pediatric Research Equity Act of 2003, Pub. L. No. 108-155, 117 Stat. 1936 (codified at 21 U.S.C. § 355c (2012)); Pediatric Research Equity Act of 2007, Pub. L. No. 110-85, 121 Stat. 866. When the pediatric exclusivity was first instituted, receiving the exclusivity required that the applicant conduct the studies in response to a written request by the FDA, whereas the applicant had the option to elect whether to respond to the FDA’s request or not. *See* 21 U.S.C. § 355a(d) (2012).

²⁰⁷ Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, §§ 402, 502, 121 Stat. 823, 866, 867; Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. No. 112-144, 126 Stat. 993 (2012).

Like all other RCSs, the pediatric exclusivity has not been free from controversy and critique. While most of the outspoken opponents of the pediatric exclusivity legislation seem to agree that some form of pediatric exclusivity is a good idea, they point out resulting waste and abuses.²⁰⁸ As can be expected, much of the critique goes to the issue of cost-effectiveness of the exclusivity, which is not surprising given that, like with most other RCSs, the legislative history of the legislation instituting the RCS (FDAMA) includes no discussion of the length of the exclusivity.

F. Regulatory Competitive Shelters in Class III Medical Devices

The second RCS regime instituted under FDAMA²⁰⁹ creates data exclusivity in data submitted to the FDA in connection with premarket approval applications (PMAs) for Class III medical devices.²¹⁰ Under this RCS, in reviewing (PMAs) for follow-on versions of previously-approved Class III medical devices, the FDA may only use data submitted in connection with the earlier application “6 years after the [original developer’s] application has been approved.”²¹¹ Medical devices are not awarded market exclusivity in addition to this six-year exclusivity period.²¹² Thus, subsequent applicants

²⁰⁸ These include: (1) the pediatric exclusivity’s lack of cost-effectiveness; (2) the fact that in its current form it tends to encourage studies mostly in highly profitable drugs for which the exclusivity constitutes a windfall, at the expense of the public; and (3) that the exclusivity is not dependent on results (in the form of labeling changes reflecting the results of the studies). *See* H.R. REP. NO. 107-227, at 56–58 (2001); 153 CONG. REC. S11831, 11837–38 (2007) (statement of Sen. Dodd).

²⁰⁹ Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (codified in scattered sections of 21 U.S.C.).

²¹⁰ Class III of medical devices includes those devices that are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury, and that with respect to which there is insufficient information to determine that regulatory controls applicable to Class I and Class II devices would provide reasonable assurance of safety and effectiveness. 21 U.S.C. § 360c(a)(1)(C) (2012). As such, Class III is the most heavily regulated tier of medical devices under FDA regulations. *Id.* Receiving a premarket approval of a Class III medical device from the FDA is subject to extensive data submission requirements. *See id.* § 360e(c)(1). Examples of Class III medical devices include artificial hearts, atrial defibrillators, cochlear implants, pacemakers, certain detection kits for life threatening pathogens (e.g., hepatitis B, hepatitis C, Human Papillomavirus), knee prostheses, and more. *See Product Classification*, FDA, www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm (last updated Feb. 9, 2015), *archived at* <http://perma.cc/BH7W-HH6>; 21 C.F.R. §§ 870.5300, 870.3610, 888.3480 (2014).

²¹¹ Food and Drug Administration Modernization Act of 1997 § 216 (codified at 21 U.S.C. § 360j(h)(4)(A) (2012)).

²¹² Apparently, the reason for the lack of market-exclusivity in this area of technology was Congress’s impression that the medical device industry was sufficiently strong “to prosper without the aid of anti-competitive rules.” *See* FOOD & DRUG ADMIN., GUIDANCE

seeking approval of their own versions of previously-approved medical devices may do so even prior to the lapse of six years from the date when the FDA approved the original device by submitting their own R&D data.

There is a dearth of legislative history pertaining to this RCS—which came to be known as “the six-year rule”—as well as its rationale.²¹³ However, the similarity of the data exclusivity instituted under the six-year rule to the RCSs mentioned earlier suggests that its purpose was also to reward the submission of clinical data regarding a particular kind of medical technology by sheltering the submitter, for a limited period of time, from competition in that technology. Additional insight as to the purpose of this RCS may be gleaned from the legislative history of the RCS regime that preceded the six-year rule, which the six-year rule replaced.

Prior to 1997, the marketing approval of medical devices was subject to a data exclusivity regime known as “the four-of-a-kind rule.”²¹⁴ Under this rule, in reviewing a PMA for a follow-on version of a medical device, the FDA was only able to refer to data submitted in connection with an earlier PMA after the lapse of one year from the entry of the fourth medical device of the same kind into the market.²¹⁵ Prior to the institution of the four-of-a-kind rule in 1990, the FDA was unable to refer to such earlier data, causing waste of R&D resources and unnecessary delays in making new medical device technologies available to the public.²¹⁶ Thus, while it is not clear what prompted Congress to replace the four-of-a-kind rule with the six-year rule, it is evident from the legislative history of the four-of-a-kind rule that the rationale for the medical device RCS was to create a regime that would facilitate use of data submitted to the FDA so as to avoid unnecessary waste and hindered accessibility to medical devices. Presumably, the institution of the six-year RCS period was meant to offset or mitigate the financial loss to medical device developers due to the use of their proprietary data and to facilitate competition in the markets for their devices. There seems to be no literature evaluating the success of the six-year rule.

ON SECTION 216 OF THE FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997, at 5 (2000).

²¹³ FDAMA § 216, which contains the six-year rule, passed in its original form and the only language in the legislative history pertaining to this section merely offers cursory description of the section. *See* H.R. REP. NO. 105-399, at 56 (1997).

²¹⁴ *See* H.R. REP. NO. 101-808, at 6–7, 27–28 (1990); CONG. RESEARCH SERV., FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997—THE PROVISIONS 31 (1998).

²¹⁵ H.R. REP. NO. 101-808, at 27–28.

²¹⁶ *Id.* at 27.

G. Regulatory Competitive Shelters Under the Biologics Price Competition and Innovation Act (BPCIA)

On March 21, 2010, Congress enacted BPCIA,²¹⁷ which laid the foundation for a regulatory pathway for the approval of biological products²¹⁸ “biosimilar to”²¹⁹ (and possibly “interchangeable with”²²⁰) approved biological products (“reference products”²²¹).²²² BPCIA institutes several RCSs, including a twelve-year market exclusivity period for original biologics²²³ and a four-year data exclusivity period for data submitted in support of the application for an original biologic.²²⁴ BPCIA further provides for a possible extension of the twelve-year market exclusivity and four-year data exclusivity (as well as the seven-year exclusivity for biological products benefitting from the RCS under the Orphan Drug Act) with an additional six-month period for having the biological product tested and approved for use in pediatric populations.²²⁵ In addition, BPCIA establishes market exclusivity

²¹⁷ BPCIA was enacted as part of the Patient Protection and Affordable Care Act. Biologics Price Competition and Innovation Act, Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. 119, 804–23 (2010).

²¹⁸ See *supra* note 155.

²¹⁹ Under BPCIA, the term “biosimilar” or “biosimilarity” means that “the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components” and that “there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.” See BPCIA § 7002(b) (codified at 42 U.S.C. § 262(i)(2) (2012)).

²²⁰ Under BPCIA, the term “interchangeable” or “interchangeability” means that “the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.” See BPCIA § 7002(b) (codified at 42 U.S.C. § 262(i)(3), (k)(4) (2012)).

²²¹ Under BPCIA, a “reference product” is the biological product previously approved by the FDA under PHSA § 351(a) against which a generic biological product is evaluated in an application submitted under BPCIA. See BPCIA § 7002(b) (codified at 42 U.S.C. § 262(i)(4) (2012)). The determination of interchangeability was designed to be the prize sought after by generic manufacturers of follow-on, generic versions of original biological products. Once made, the interchangeability determination facilitates the “interjection” of the generic product into the existing market for the original product and enables it to benefit from the reference product’s client base.

²²² BPCIA § 7002(a) (codified at 42 U.S.C. § 262 (2012)). BPCIA sets up numerous elaborate conditions and requirements for the establishment of biosimilarity to a reference product and interchangeability thereof. See *id.* (codified at 42 U.S.C. § 262(k)(2)–(4) (2012)).

²²³ BPCIA § 7002(a) (codified at 42 U.S.C. § 262 (2012)). Under this exclusivity, the FDA may not approve follow-on versions of a previously approved biologic until after twelve years from the date of approval of the reference product. *Id.*

²²⁴ *Id.* (codified at 42 U.S.C. § 262). During this period, generic applicants may not submit applications for the approval of their versions of biologics biosimilar to reference products. 42 U.S.C. § 262(k)(7)(C).

²²⁵ BPCIA § 7002(g) (codified at 42 U.S.C. § 262(m) (2012)).

periods of twelve to forty-two months for a generic manufacturer of a first biological product approved as interchangeable with the reference product.²²⁶

The enactment of BPCIA was preceded by a boisterous battle with proponents of the biotechnology industry on one side and advocates of the generic industry on the other.²²⁷ As a result, BPCIA has a rich background and legislative history that offer a unique peek at many facets of its RCS regime, including the length of BPCIA's RCSs in general and that of the twelve-year market exclusivity in particular.

While the BPCIA RCS regime was fashioned with the Hatch-Waxman RCS regime in mind, unlike Hatch-Waxman's five-year NCE exclusivity, the twelve-year market exclusivity under BPCIA was not devised as an added incentive for product developers where patent protection is unavailable or where there is too little patent life remaining.²²⁸ Rather, the twelve-year exclusivity was vehemently lobbied for and crafted as a fallback option to patents, serving as "litigation insurance" in case of failure to enforce patents protecting biological products.²²⁹ The reason for the need for such "litigation insurance" was that biologics developers viewed patent law's protections of their proprietary interests as inadequate.²³⁰ In other words, while the Hatch-Waxman's NCE exclusivity was meant to *supplement* patents, the twelve-year market exclusivity under BPCIA was designed to replace patents. The determination of the desired length of the market exclusivity as twelve years was based on product developers' perception that "the effective patent life for pharmaceuticals—the time remaining following FDA approval—is approximately eleven to twelve years."²³¹ Thus, based on these assumptions,

²²⁶ BPCIA § 7002(a) (codified at 42 U.S.C. § 262 (2012)). The length of a market exclusivity period afforded to such a first generic manufacturer depends on several factors, including: (1) whether a patent infringement lawsuit was filed subsequent to the filing of the biosimilar application under 42 U.S.C. § 262(k) for the approval of a version of the original biological product; (2) the outcome of such lawsuit; and (3) the marketing status of such product. *Id.*

²²⁷ See Heled, *supra* note 13, at 437 & nn.69–70; see also H.R. 6257, 109th Cong. (2006) and S. 4016, 109th Cong. (2006) (introduced, respectively, by Rep. Waxman and Sen. Schumer as a way to "start the conversation" about a framework for the approval of generic versions of biologics); H.R. 1038, 110th Cong. (2007) (reintroduced version of H.R. 6257, 109th Cong. (2006)); S. 623, 110th Cong. (2007) (reintroduced version of S. 4016, 109th Cong. (2006)).

²²⁸ See *supra* note 168 and accompanying text.

²²⁹ Proponents of long product-exclusivity periods in biological products have described such exclusivity as an "insurance policy" in case patents would fail. See *supra* note 86.

²³⁰ See Heled, *supra* note 13, at 438 & n.74, 451 & n.142 (reviewing the arguments in favor of a long product-exclusivity period for biologics developers).

²³¹ Gitter, *supra* note 13, at 616; see also FED. TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION v–vii (2009), available at <https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follo-w-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf>, archived at <http://perma.cc/HG4Q-6FD3> ("The economic model put forth by pioneer drug

the purpose of the twelve-year market exclusivity for biologics developers was that only such a long period of market exclusivity would provide developers of original biologics with sufficient incentive to innovate in new biologics.²³²

The BPCIA RCS regime, and, especially, the twelve-year market exclusivity RCS, have been the subject of much critique.²³³ Many have expressed concern that BPCIA fails to strike a balance between competition and innovation and that its RCS regime (and the twelve-year market exclusivity period in particular) creates windfalls to biologics developers and would make it very difficult or even unfeasible for generic competition to enter the biologics market.²³⁴ However, it is still too early to determine whether the BPCIA RCS regime successfully realized its goal of opening the biologics market to generic competition while maintaining sufficient incentives for innovation.²³⁵

manufacturers to justify [a 12 to 14-year exclusivity period] is based on the average time required to recoup the investment to develop and commercialize a typical biologic drug.”); Henry Grabowski, *Data Exclusivity for Biologics: What Is the Appropriate Period of Protection?*, 10 AM. ENTERPRISE INST. FOR PUB. POL’Y RES. HEALTH POL’Y OUTLOOK, Sept. 2009, at 4–5, available at <http://www.aei.org/wp-content/uploads/2011/10/10-HPO-Grabowski-Sep08-g.pdf>, archived at <http://perma.cc/Y6AR-CD6C> (“The average [product] exclusivity period for small molecule drugs in the United States is approximately twelve years.”).

²³² See *Safe and Affordable Biotech Drugs: The Need for a Generic Pathway: Hearing Before the H. Comm. on Oversight and Gov’t Reform*, 110th Cong. 161–76 (2007) (statement of Henry Grabowski); Kathleen R. Kelleher, *FDA Approval of Generic Biologics: Finding a Regulatory Pathway*, 14 MICH. TELECOMM. & TECH. L. REV. 245, 256 (2007) (“Some have suggested that a 12-year [product] exclusivity for pioneer biologics would be optimal because traditional drugs generally have slightly under 12 years of [product] exclusivity due to patent protection.”); Jeremiah J. Kelly & Michael David, *No Longer “If,” but “When”: The Coming Abbreviated Approval Pathway for Follow-On Biologics*, 64 FOOD & DRUG L.J. 115, 139–40 (2009) (“A 12 to 14 year period of innovator exclusivity is not arbitrary; studies have shown that the point at which an innovator biological drug becomes profitable (the ‘break-even’ point) is between 12.9 and 16.2 years.”).

²³³ See McMahon, *supra* note 67, at 680–81 (arguing that BPCIA, as enacted, reflects what he describes as legislative imprudence).

²³⁴ See *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the H. Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 17 n.3 (2009) (statement of Bruce A. Leicher); Brill, *supra* note 26, at 7, 8 & 11; Kotlikoff, *supra* note 165, at 6 (arguing that granting developers of original biologics exclusivity periods of twelve to fifteen years would create overly long monopoly periods that would distort the economy of pharmaceuticals and calling for limiting exclusivity periods in biologics to lengths such as those granted under the Hatch-Waxman Act); McMahon *supra* note 67, at 671–75 (arguing that the generic exclusivity under BPCIA is worthless and therefore illusory).

²³⁵ As of January 2015, the FDA has not approved any biosimilar version of any reference product. On January 7, 2015, the FDA Oncologic Drugs Advisory Committee (ODAC) voted in favor of recommending the approval for marketing of its follow-on filgrastim. See Media Release, Novartis Global, Sandoz Biosimilar Filgrastim Recommended for Approval by FDA Oncologic Drugs Advisory Committee (Jan. 7,

H. Regulatory Competitive Shelters in New Antibiotics

On July 9, 2012, as part of the Food and Drug Administration Safety and Innovation Act (FDASIA), President Obama signed into law the Generating Antibiotic Incentives Now (GAIN) Act.²³⁶ Under the GAIN Act, once a drug has been designated as a “qualified infectious disease product,”²³⁷ any and all exclusivities applicable to that drug under the Hatch-Waxman Act and Orphan Drug Act are to be extended by five years.²³⁸ Thus, for example, if a drug product contains an active pharmaceutical ingredient (API) that is considered a new chemical entity under the Hatch-Waxman Act, and the API is also, possibly later, recognized as a “qualified infectious disease product” under FDASIA, the FDA may not accept applications for generic versions of this product for a period of ten years from the original date of approval—five years for the original NCE exclusivity²³⁹ and another five years under FDASIA. Similarly, if the new product is approved by the FDA for the treatment of a rare disease under the Orphan Drug Act, then the seven-year exclusivity under the Act is extended by another five years under FDASIA for a total of twelve years of market exclusivity.²⁴⁰ The purpose of the GAIN Act’s RCS was to provide additional incentives for the development of anti-bacterial products in light of an existing and ongoing unmet public need for antibiotic products to fight serious bacterial infections that are resistant to existing antibiotics.²⁴¹

2015), www.novartis.com/newsroom/media-releases/en/2015/1885139.shtml, archived at <http://perma.cc/2B2U-M7G2>. If approved, Sandoz’s filgrastim will be the first biosimilar product in the United States.

²³⁶ Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, §§ 801–06, 126 Stat. 993, 1077–82 (2012) (codified in scattered sections of 21 U.S.C.).

²³⁷ A “qualified infectious disease” product is defined as “an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens or any other qualifying pathogens” as decided by the Secretary based on a weighing of considerations enumerated in FDASIA and consultation with relevant experts and agencies. *See id.* §§ 801(f)–(g).

²³⁸ *Id.* §§ 801(a)–(b); *see also supra* Parts III.A–B. Notably, the GAIN Act RCS regime is different from proposals for transferable intellectual property rights (TIPRs) in that the five-year RCS is not transferable to products other than the antibiotic developed. In that respect, the GAIN Act RCS might suffer from shortcomings similar to those raised by regular patent rights in the context of antibiotic pharmaceuticals. *See supra* Aaron S. Kesselheim & Kevin Outterson, *Improving Antibiotic Markets for Long Term Sustainability*, 11 YALE J. HEALTH POL’Y L. & ETHICS 101, 132–33 (2011); Parts III.B–C. On the other hand, the five-year RCS instituted under the GAIN Act is much longer than the six to twenty-four months proposed as a recommended period for TIPRs. Kesselheim & Outterson, *supra*, tbl. 2, at 148.

²³⁹ *See supra* note 167 and accompanying text.

²⁴⁰ *See supra* note 146 and accompanying text.

²⁴¹ *See* H.R. REP. NO. 112-495, at 34 (2012); 158 CONG. REC. S4625 (2012) (statement of Sen. Menendez).

It is still much too early to evaluate the effectiveness and success of the GAIN Act RCS regime. Yet it is worth mentioning that, like the pediatric exclusivity, the GAIN Act includes an inherent process for the reassessment of the incentives afforded under the Act, to be initiated five years from its enactment.²⁴²

As is the case with most RCS regimes, the legislative history of the GAIN Act includes no discussion of the actual length of the RCS or an indication as to why five years was chosen as the proper length for this RCS, rather than three or seven years, for example. Nonetheless, the GAIN Act RCS regime reflects sophistication in the use of RCSs as an instrument of innovation policy.²⁴³

IV. WHY ARE REGULATORY COMPETITIVE SHELTERS, AS A PHENOMENON, LIMITED ALMOST EXCLUSIVELY TO FDA REGULATION?

The fact that seven of the eight RCS regimes discussed earlier are administered by the FDA, and only one by a different agency, raises questions regarding the general applicability of RCSs (or, at the very least, innovation-incentivizing RCSs).²⁴⁴ Namely, are RCSs only suitable for use in the context of chemical and biomedical arts? Can RCS regimes be successfully implemented outside of the FDA, or are RCSs, by virtue of being tailored to create incentives for certain industries, expected to be limited almost exclusively to FDA regulation?

There does not seem to be anything unique about RCSs that renders them exclusively suited for only certain areas of technology. Further, on their face, there does not appear to be anything in the specific areas of technology subject to RCS regimes that makes them uniquely suitable for RCSs.

The prevalence of RCSs in regulatory frameworks administered by the FDA may, however, be at least partly attributable to the increased value that our society places on public health and on safety of biomedical products, and the belief that clinical trials of new products (which FDA RCSs are meant to incentivize) advance these goals.²⁴⁵ Another way of looking at this explanation

²⁴² Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 805, 126 Stat. 993, 1080–81 (2012) (codified at 21 U.S.C. § 360a (2012)).

²⁴³ This may be testament not only to the many beneficial qualities of RCSs as a policy tool but also to the GAIN Act drafters' ability to use these qualities in a skillful manner.

²⁴⁴ Notably, another significant RCS regime that was recently proposed but has not been enacted was also meant to be administered by the FDA. *See* Modernizing Our Drug & Diagnostics Evaluation and Regulatory Network Cures Act of 2011 (MODDERN Cures Act), H.R. 3497, 112th Cong. (2011) (proposing an extension of the RCSs under the ODA, Hatch-Waxman Act, and BPCIA by an additional six to twelve months for the development of diagnostics for the treated condition and a new fifteen-year market exclusivity for pharmaceuticals approved for use in "dormant therapies").

²⁴⁵ *See* Eisenberg 2007, *supra* note 15, at 372–73 ("We value health, and we believe that high quality biomedical science will have public health payoffs. FDA regulation similarly promotes . . . the conduct of scientifically rigorous clinical trials of drugs.").

is that the relatively high financial burden imposed under FDA law on technology developers may require additional incentives beyond those afforded under patent law to undertake the financial risks associated with drug development. In this regard, FDA regulation may be “fertile soil” for RCS regimes because of the high costs of technological innovation imposed under FDA law and the high stakes involved in such endeavors.²⁴⁶

The fact that existing RCS regimes are almost exclusive to FDA law could also be attributed to the success of the ODA and Hatch-Waxman RCS regimes that made RCSs “visible” as a public policy tool for drafters of legislation who tend to concentrate their efforts on pharmaceutical and biomedical technologies.²⁴⁷ It may also be that RCSs’ many advantages over patents have made them popular with FDA constituents—primarily the pharmaceutical and biotechnology industries—which tend to rely heavily on patents as a critical element in their business models and therefore spend vast amounts of money lobbying for such regimes. Further, the expertise acquired by the FDA over the years in evaluation of products as well as in the administration of RCS regimes may have served to make it an attractive candidate to administer more and more such regimes. It is quite possible that all of the above play at least some role in the prevalence of RCSs in FDA legislation.

Regardless, nothing in these explanations seems to reflect negatively on the prospects of success of RCS regimes in other areas of technology regulated by different administrative agencies. Indeed, there do not seem to be any objective impediments to the institution of RCS regimes in other areas of technology, which may include, for example, genetically modified food crops (regulated by the EPA), safety features for cars (regulated by the National Highway Traffic Safety Authority), new medical research tools (not currently regulated, but could be regulated by the National Institutes of Health), novel synthetic food technologies like in-vitro meat (regulated by the FDA), and more.

V. CONCLUSION

Regulatory competitive shelters are competitive advantages resulting from statutory bars on regulatory action where such action is otherwise mandated and would have taken place but for the triggering of the bars. The RCSs discussed in this Article are not and ought not be viewed as an array of separate exclusivity regimes, but rather as a single regulatory phenomenon whose members share several defining characteristics, including: (1) a common purpose of creating incentive for technological innovation, (2) limitation in time, (3) automatic onset upon the fulfillment of certain

²⁴⁶High regulatory costs alone, however, are not unique to the context of FDA regulation and, thus, cannot provide full explanation to the aggregate of RCS regimes in FDA law.

²⁴⁷Rep. Henry Waxman, for example, has been involved in the drafting and promotion of many RCS regimes.

legislative, or regulatory requirements without a need for an affirmative grant, and (4) the lack of conferral of any identifiable right such that the benefits of RCSs are incidental and “automatically enforced” by the administering agency. Some additional features shared by most RCSs are their (5) low susceptibility to legal challenges, (6) high level of specificity to particular circumstances, (7) flexibility as a public policy tool, (8) highly clear boundaries leading to legal certainty, (9) low risk of imposing impediments on subsequent R&D, and (10) low administrative cost.

The mechanism by which the RCSs discussed herein achieve their goal, as explained in this Article—whether market exclusivity, data exclusivity or generic exclusivity—is not as straightforward as that of other government benefits, but is mostly highly effective. As a result, since their emergence in the late 1970s, RCSs have become increasingly prevalent in the context of regulated technologies, primarily (but not necessarily exclusive to) pharmaceuticals, where their many advantages, especially over patents, have made them popular among industry stakeholders. Of the eight RCS regimes and fifteen RCSs reviewed in this Article, seven regimes and fourteen RCSs are administered by the FDA in the context of biomedical technologies. However, there seems to be no objective impediment to the institution and implementation of RCS frameworks in the context of other technologies, including ones not regulated by the FDA. Rather, the advantages of RCSs make them an attractive public policy tool in other areas of regulated technology where there is a need to create incentives for technological innovation and disclosure of pertinent information thereof.

Yet, their relative novelty as a regulatory phenomenon makes certain aspects of RCSs insufficiently clear and requires further research, including (1) RCSs’ cost-efficiency and effectiveness in achieving their goals as opposed to other alternatives, (2) their potential to serve as an alternative to patents, (3) how to minimize the risk of anticompetitive abuses of RCSs, (4) the development of a methodology for reason-based determination of appropriate length for specific RCSs,²⁴⁸ and (5) what other areas may be suitable for the institution of RCS regimes and what criteria should be employed in making such determinations. Other interesting issues that may merit further inquiry include the ability of RCS-beneficiaries to transfer and extinguish their RCSs, the possible classification of RCSs (and especially iiRCSs)²⁴⁹ as property or intellectual property, and RCSs’ status under the Constitution’s Progress Clause.²⁵⁰

²⁴⁸ Efforts in this regard may be informed by important recent work by Budish, Roin and Williams. See Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Fixed Patent Terms Distort Innovation? Evidence from Cancer Clinical Trials* 35 (Initiative on Global Markets, Working Paper No. 97, 2013) (proposing parameters and consideration for determination of optimal differential patent terms; indicating that FDA RCSs provide such differential patent terms in the context of pharmaceuticals).

²⁴⁹ See *supra* note 3.

²⁵⁰ U.S. CONST. art. I, § 8, cl. 8.

While the “golden age” of RCSs was the 1980s, renewed popularity of RCSs in federal regulatory regimes (both legislated and proposed) over the last few years may indicate that we should expect to see more of them in future legislation. It is therefore necessary to start discussing RCSs per se, outside of and beyond the context of particular regimes so that we may derive their full benefits and avoid their perils.